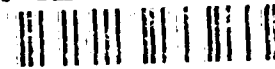


ANNUAL PROGRESS REPORT

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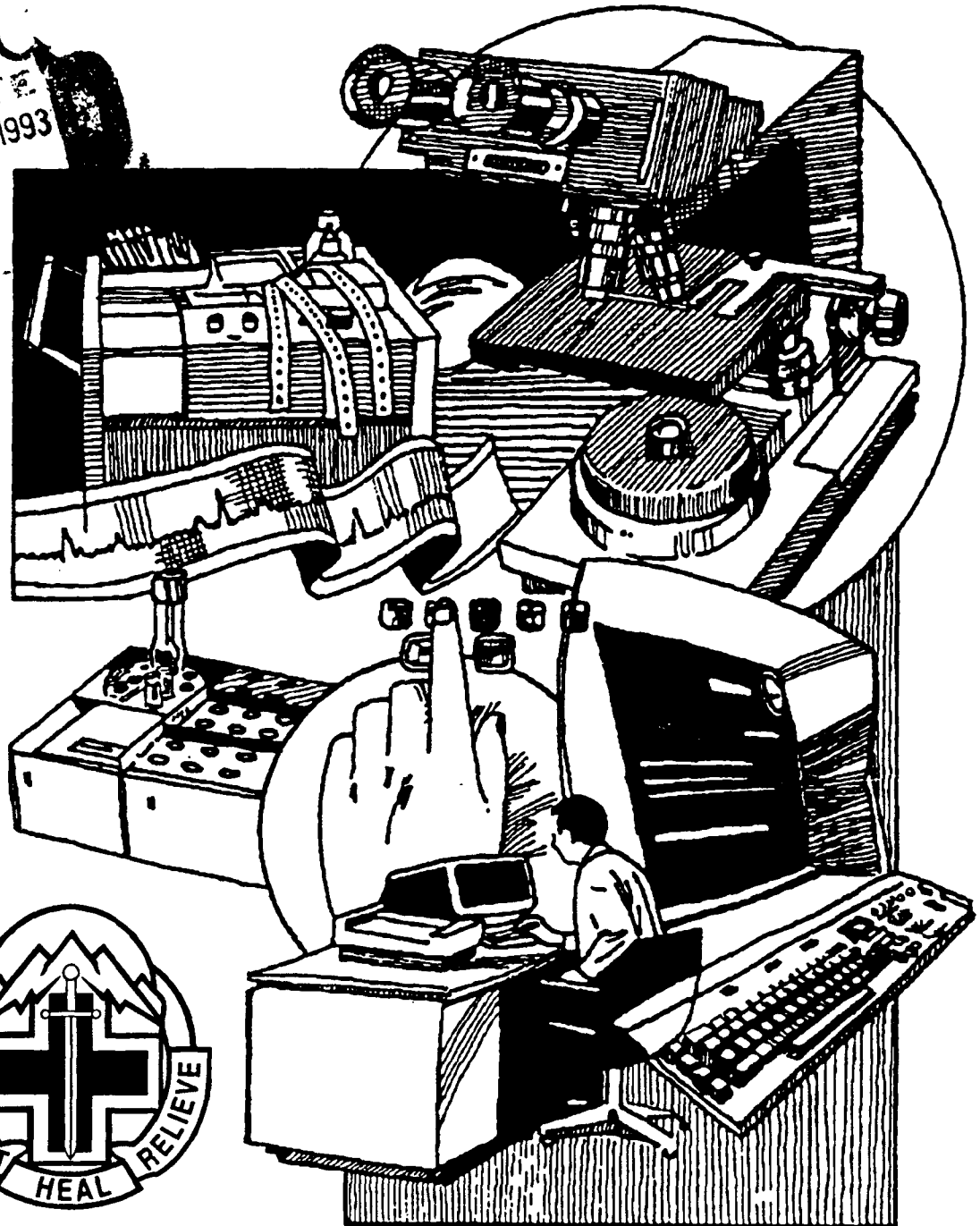
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CLINICAL INVESTIGATION PROGRAM

30 SEPTEMBER 1992

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DEPARTMENT OF CLINICAL INVESTIGATION

Fitzsimons Army Medical Center
Aurora, Colorado 80045-5001

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ANNUAL PROGRESS REPORT

30 SEPTEMBER 1992

**DEPARTMENT OF CLINICAL INVESTIGATION
FITZSIMONS ARMY MEDICAL CENTER
AURORA, COLORADO 80045-5001**

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FOREWORD

This report identifies the research activities conducted by Fitzsimons Army Medical Center investigators through protocols approved by the Institutional Review Committee and registered with the Department of Clinical Investigation during Fiscal Year 1992 along with other known presentations and publications by FAMC professional staff.

The research protocols described in this report were conducted under the provisions of AR 40-38, Clinical Investigation Program, AR 40-7, Use of Investigational Drugs in Humans, AR 40-023, as amended, Management of Clinical Investigation protocols and Reports, to insure the medical safety, well being, preservation of rights and dignity of human subjects who participated in these investigations. In conducting the research described in this report, the investigator(s) adhered to AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs and the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee or the Guide for Laboratory Animal Resources, National Academy of Sciences, National Research Council.

The Department of Clinical Investigation is grateful to the Center's Commander, BG Thomas E. Bowen and all of the professional and administrative staff for departments and directorates who have furthered the mission of Clinical Investigation Department at Fitzsimons through their cooperation and extra effort as reflected in this report. I should like to particularly recognize the outstanding work and dedication and wholehearted corroboration of all of the Services' within Clinical Investigation Department, the Assistant Chief, LTC Michael Lieberman, the Chief, Microbiology Service, LTC Richard Harris, the Research Protocol Specialist, Ms. Marcia Bilak, and Ms. Chris Montoya, Secretary, without whose assistance and support beyond the call of duty this year's progress and its report would not have been possible.

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KENNETH E. SHERMAN
MAJ, MC
Chief, Department of
Clinical Investigation

UNIT SUMMARY

Clinical Investigation efforts by FAMC personnel in FY 92 culminated in the publication of 215 articles and 157 presentations and lectures at national, international, and regional scientific meetings. As of 30 September 1992 there were 361 research protocols on the DCI register.

Objectives:

To encourage the performance of clinically-oriented investigation by personnel assigned to the Fitzsimons Army Medical Center (FAMC). To aid in the planning, development, support, and execution of experimental clinical studies, both in patients and by directly related laboratory work, into the clinical problems of significant concern in the health care of members of the military community. To provide physician experience in research and investigative procedures by furnishing a highly educated and trained staff of specialists, laboratory facilities, administrative services and funding for: supplies, equipment, consultants, publications and reprints. To achieve continuous improvement in the quality of patient care by providing an atmosphere of inquiry, maintaining high professional standing and accreditation of advanced health programs.

The Clinical Investigation Program differs from Medical Research and Development in that the emphasis is on the health care problems existing in our patient populations, i.e., active duty, retired, and dependents and not solely on medical problems affecting combat readiness and the fighting strength. It is, by its nature, an integral part of the triad of patient care and medical education. It promotes and supports the finest ideals and traditions of Military Medicine and enhances the vitality of the teaching programs which in turn elevates the standard of medical care. The research program operates on the premise that all approved protocols will be supported to the fullest extent allowed by current funding. This concept allows for a larger number of physicians and ancillary personnel to participate in research rather than as in the grant system used elsewhere. This means that virtually every investigator is given a chance to pursue his research without having to compete for funds with "established" names in the field.

Technical Approach:

This support is carried out under the aegis of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; AR 70-25, Use of Volunteers as Subjects in Research; AR 70-18, Laboratory Animals, Procurement, Transportation, Use,

Care, and Public Affairs; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports, as amended; FAMC Reg 40-18, Institutional Review Committee. This Department provides guidance, assistance, and coordinates the FAMC program with higher headquarters.

Manpower: current authorized strength is outlined.

| Description | Grade | MOS | Br | Auth | Req | Act | Name | Rank |
|----------------------|-------|-------|----|------|-----|-----|-------------|------|
| C, Dept Clin Inv | 04 | 60G8N | MC | 1 | 1 | 1 | Sherman, K. | MAJ |
| Clin. Rsch. Coord. | 06 | | MC | | | 1 | Cucinell | COL |
| NCOIC, DCI | E6 | 01H3R | | 1 | 1 | 1 | Stinnett | SSG |
| Research Prot Sp | 09 | 0301 | GS | 1 | 1 | 1 | Bilak | |
| Secretary | 06 | 0318 | GS | 1 | 1 | 1 | Montoya | |
| Med Technologist | 11 | 0644 | GS | 0 | 1 | 1 | Rush | |
| Nurse Specialist | 11 | 0610 | GS | | | | Palestro | |
| Nurse | 09 | 0610 | GS | | | | Ressman | |
| C, Animal Res Svc | 04 | 64C9B | VC | 1 | 1 | 1 | Banks | MAJ |
| NCOIC, ARS, DCI | E6 | 91T3R | | 1 | 2 | 1 | Barrett | SSG |
| Animal Care NCO | E5 | 91T2R | | | | | Bowers | SGT |
| Animal Care NCO | E5 | 91T2R | | | | | Zobrist | SGT |
| OR NCO, ARS | E5 | 91D2R | | 1 | 1 | 1 | Shiver | SGT |
| Animal Care Foreman | 04 | 5048 | WS | 1 | 1 | 1 | Jones | |
| Animal Caretaker | 06 | 5408 | WG | 1 | 3 | 3 | Chase | |
| | 05 | | | | | | Hitchcock | |
| | 05 | | | | | | Giese | |
| C, Biochem Svc | 03 | 68C9C | MS | 1 | 1 | 1 | Schofield | CPT |
| NCOIC, Biochem | E5 | 92B2R | | 1 | 1 | 1 | Zahn | SGT |
| Bio Sci Asst | E4 | 01H1R | | 1 | 3 | 1 | Schaphorst | SPC |
| Med Technologist | 09 | | GS | 1 | 1 | 1 | Vacant | |
| Research Chem | 11 | 1320 | GS | 2 | 3 | 3 | Noble | |
| | | | | | | | Sherva | |
| C, Biomet & Resh | 05 | 68T00 | MS | 1 | 1 | 1 | Sherman, R. | LTC |
| Psychophysiol. Tech. | 09 | 0181 | GS | | | | Evans | |
| Psychophysiol. Tech. | 07 | 0181 | GS | | | | | |
| Statistical Asst. | 05 | 1531 | GS | | | | Caminer | |
| C, Cell Phys Svc | 13 | 1320 | GS | 1 | 1 | 1 | Jackson, R. | |
| NCOIC, CPS | E6 | 01H3R | | 1 | 1 | 1 | Cruz-Saez | SSG |
| Bio Sci NCO | E5 | 01H2R | | 1 | 2 | 1 | Johnson | SGT |
| Research Biologist | 11 | 0404 | GS | 1 | 1 | 1 | Mercill | |

| Description | Grade | MOS | Br | Auth | Req | Act | Name | Rank |
|---------------------|-------|-------|----|------|-----|-----|--|------|
| C, Immunology Svc | 05 | 68T00 | MS | 1 | 1 | 1 | Lieberman | LTC |
| Microbiologist | 11 | 0403 | GS | 3 | 3 | 3 | Lima Hoyt | |
| Microbiologist | 09 | 0403 | GS | 1 | 1 | 1 | Meuhlbauer | |
| Med Technologist | 09 | 0644 | GS | 7 | 7 | 5 | Ramirez Pinney Sachanandani Granata | |
| C, Micro Svc | 05 | 68A00 | MS | 1 | 1 | 1 | Harris | LTC |
| NCOIC, Micro/Immuno | E6 | 01H3R | | 1 | 1 | 1 | Brady | SSG |
| Bio Sci NCO | E5 | 01H2R | | 1 | 1 | 1 | Sipple | SGT |
| Microbiologist | 11 | 0403 | GS | 1 | 1 | 1 | Paine | |
| Microbiologist | 09 | 0403 | GS | 2 | 3 | 3 | Morse | |
| Microbiologist | 09 | 0403 | GS | | | | Andreatta | |
| Med Technologist | 09 | 0644 | GS | 1 | 1 | 1 | Schlichtemeier | |
| Med Technician | 07 | 0645 | GS | 2 | 2 | 1 | Nelson | |
| C, Molecular Bio | 13 | 1320 | GS | 1 | 1 | 1 | Gutierrez | |
| Research Chem | 11 | 1320 | GS | 1 | 1 | 1 | O'Brien | |

Funding

The OMA costs have not been itemized by protocol number because it is not feasible or practical to do so.

| | FY 90 | FY 91 | FY 92 |
|------------------------------|------------|------------|------------|
| OMA Civilian Personnel | 834,529. | 1,129,389. | 1,067,960. |
| Contracts/Supplies | 453,777. | 44,019. | 319,322. |
| Ceep Equipment | 64,424. | 77,859. | 55,183. |
| Travel | 9,978. | 28,928. | 9,624. |
| Military Personnel | 754,499 . | 813,626. | 1,007,988. |
| Rentals | | 10,178. | 400. |
| OPA MEDCASE | 740,811. | 262,529. | 220,366. |
| Civilian Consultants FY 90 - | \$828.00 | 300. | 1,850. |
| Publication Costs FY 90 - | \$9,081.00 | 8,678. | 12,026. |

Personnel

| | Required | Authorized | Assigned |
|------------|----------|------------|----------|
| Officers | 5 | 6 | 7 |
| Enlisted | 12 | 13 | 11 |
| Civilian | 23 | 34 | 29 |
| VA Grant | 2 | 2 | 2 |
| Grant Emp. | 3 | 3 | 3 |

GRANTS for FY 92

- (1) Prospective collection and banking of lymphocytes and clinical data on HIV infected individuals taking antiretroviral agents.
\$148,387.
- (2) Work of breathing as a predictor of failure to wean from mechanical ventilation in patients with severe chronic obstructive pulmonary disease.
\$19,731.
- (3) Analysis of wounds by evaporative water loss in man.
\$29,438.
- (4) Etiology and progression of acute muscle tension related low back pain occurring during sustained activity including combat training exercise.
\$90,626.
- (5) Use of body surface heat patterns for predicting and evaluating acute lower extremity pain among soldiers.
\$48,942.
- (6) Efficacy of passive immunization in the prevention of infection due To klebsiella pneumoniae and pseudomonas aeruginosa. (IVIG Study)
\$54,300.
- (7) Extrinsic positive end-expiratory pressure (PEEP) effects on functional residual capacity in normal subjects and in ventilated patients experiencing air trapping.

USAMRDC Grants Total: \$391,424.
Veterans Administration (VA) - VA Funds (Sherman) \$79,000

FACT

| | 1991 | 1992 | TOTALS |
|------------------------|-----------|------------|------------|
| Personnel | 27,711.60 | 80,976.30 | 108,687.90 |
| Equipment/ Supplies | 20,835.02 | 12,678.72 | 33,513.74 |
| Trips | 1,644.00 | 7,522.00 | 9,166.00 |
| TOTALS | 50,190.62 | 101,177.02 | 151,367.64 |

HUGH MAHON LECTURESHIP AWARD COMPETITION - 1992

This student research award was established in 1950 and honors the late Colonel Hugh W. Mahon, MC, USA, Retired, who was Chief, Department of Pathology, Fitzsimons Army Medical Center, for 12 years. The lectureship consists of the presentation of papers judged best from among those submitted by officers in training status at FAMC.

The Hugh Mahon Lectureship Award Competition is divided into the categories of retrospective or prospective clinical studies, basic laboratory investigations, and literature reviews/case reports. This year there were a total of 38 submissions; 8 manuscripts in the laboratory category, 18 in clinical studies, and 12 case reports/literature reviews. This is the second largest number of submissions. In 1991 there were 34; in 1990, 36; in 1989, 41; in 1988, 23 and in 1987, 18.

Judging was done by the members of the FAMC clinical teaching staff and a panel of distinguished university and community professors. Manuscripts were scored on originality and medical significance, experimental design, presentation and interpretation of data, and literary quality.

A Grand Prize Winner was chosen from among the five finalists in all three categories based on the presentation and question-and-answer period during the Hugh Mahon Lectureship Conference. The finalists for 1992 are as follows:

Clinical

1st place: The Effect of Terfenadine on Urination.
Madhukar K. Punja, MAJ, MC, Fellow, Allergy-Immunology.

2nd place: Endocrine Profiles for Outcome Prediction From Intensive Care. Mark J. Jarek, CPT, MC, Resident, Internal Medicine.

Laboratory

1st place: The Role of the Upper Airway in the Development of Subglottic Pressure During Acute Lung Injury.
Michael T. McCormack, MAJ, MC, Fellow, Pulmonary.

Grand Prize and 2nd place: Effects of Beta-Adrenergic Antagonists on Intracellular Cyclic Nucleotide Generation in Guinea Pig Airway Smooth Muscle.
Michael A. O'Connell, MAJ, MC, Fellow, Allergy-Immunology.

Case Report/Literature Review

One Prize Only: Different Manifestations of the Antiphospholipid Antibody Syndrome in a Family with Systemic Lupus Erythematosus.
Kimberly P. May, CAPT, USAF, MC, Fellow, Rheumatology.

Animal Resources Service - FY 92

This service continued efforts begun during last FY to upgrade and improve the care provided to the research livestock assigned and to the support provided the medical center staff. Currently with an active training protocol listing, this service provides regular training for various surgical skills (soft and hard tissue, gross and micro-surgery) and peri-operative requirements (intubation training and suturing skills). Research efforts have continued with significant support focused toward the orthopedic residency program, otolaryngology, dermatology, and rheumatology.

Additional personnel were gained this year for a year-end total of 3 Animal Care Specialists, 1 Operating Room Technician, 1 Facility Manager, and 3 Animal Care Providers. Sufficient personnel has allowed accomplishment of supplementary support features (socialization of all animals, innovative housing arrangements, facility self-help improvements, etc.).

The work load of this service continued to increase resulting in an average of just under 600 procedures a month. This resulted in 4 publications (with others currently under review for consideration) and 16 presentations during this FY.

Mercury thermometers were replaced by digital max-min thermometers throughout the animal housing facility to eliminate the risk of exposure to this dangerous element.

A magnetic door lock security system with card reader access was installed on all exterior doors of the animal facility and on one door inside the facility between the administrative area and animal housing areas.

The long-awaited steam removal hoods were finally installed, providing for the immediate evacuation of steam generated by the cage washer when a door is opened. This protects paint on walls and ceilings adjacent to the cage washer from steam damage.

A new air conditioner was installed along with the steam removal system to provide makeup air, and a new, larger building air conditioner was installed to replace the original undersized units which had become inoperative and were not economically repairable.

Mr. Jones attended the 42nd AALAS Annual Meeting in Buffalo, NY in October. MAJ Banks attended the Academy of Surgical Research Annual Meeting in Chicago, Illinois. MAJ Banks, Mr. Jones, and Ms. Chase attended the 4th Annual Clinical Investigation Postgraduate Short Course in San Antonio, TX in April. Mr. Jones and Ms. Giese attended the AALAS Mile High Branch Annual Meeting in Silver Creek, CO in May. Ms. Giese was certified by AALAS as a Laboratory Animal Technologist in September.

MAJ Banks presented 12 papers during this year: Ethical Animal Utilization and the Veterinarian, Army Medical Department Advanced & Basic Medical Officer Courses, Ft. Sam Houston; Emergencies and Critical Care of the Research Surgical Patient, Surgical Research Specialist Symposium, Academy of Surgical Research, Chicago, Illinois; Yucatan Miniature Swine as a Model System for the Study of Vocal Fold Vibratory Function; 8th Annual Scientific Meeting of the Academy of Surgical Research; Chicago, Illinois; Attachment of HA-Coated & Un-coated Implants Is Influenced By Coumadin Administration, 8th Annual Scientific Meeting of the Academy of Surgical Research; Chicago, Illinois; Gelfilm Barrier for Prevention of Post-Parotidectomy Frey's Syndrome: A Human & Animal Model Experience, American Academy of Otolaryngology, Washington DC; Humane Society Technician Symposium: Rabbit Housing, Nutrition, Anesthesia, Peri-op Surgical Care, Physical Examination, Zoonotic Diseases and Proper Methods of Euthanasia, Denver Dumb Friends League, Denver, Colorado; Modern Animal Facilitated Research and the Adversary, Mile High Branch Symposium of the American Association of Laboratory Animal Science, Denver, Colorado; Review of the Animal Rights Movement: Its Goals and Strategies, Briefing for the Military Veterinary Western States Conference, San Antonio, Texas; Attachment of HA Coated & Uncoated Porous Implants as Influenced by Methotrexate and Coumadin in a Goat Model, Orthopedic Research Society, Washington DC; Effect of Coumadin on Interface Mechanics of Hydroxyapatite-Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model, Society of Military Orthopedic Surgeons, El Paso, Texas; Evaluation of the Goat Patellar Tendon After Harvest of its Middle Third (Chronic Survival Review), Society of Military Orthopedic Services, El Paso, Texas; and A Review of the Animal Rights Movement: Its Goals and Strategies, Briefing for the Assistant Secretary of Defense for Health Affairs, The Pentagon.

Service personnel were involved in the support of and eventual publication of the 5 manuscripts: The Effect of Partial Upper Airway Bypass on the Development of Subglottic Pressure During Acute Lung Injury in the Sheep; Reflections of an IACUC Veterinarian; Correlation of the Vocal Fold Vibratory Pattern with the Post-operative Surgical Wound in the Miniswine Model; Non-Human Primates: Parasitic and Infectious Diseases; and A Modified Reversible Intestinal Tie - Adult Rabbit Diarrhea (RITARD) Model in the Rabbit.

Biochemistry Service - FY 92

The Biochemistry Service has undergone several major changes during the past year following the arrival of a new Chief in October. These changes came across the board, resulting from Departmental reorganization, personnel changes, clinical requirements affecting mission efforts, improvements to the facility, and new equipment acquisitions.

The most significant of these was the establishment of a separate Molecular Biology Service within DCI. The molecular biology laboratory under Dr. Gutierrez, along with Ms. O'Brien, began functioning as an independent Service in May 1992. The focus of efforts in the laboratory continues to be detection and measurement of Hepatitis C virus load and HIV using Polymerase Chain Reaction (PCR) technology, as well as continued work characterizing a unique TRH sensitive thyroid cell line begun in conjunction with Dr. Homer Lemar, Endocrine Clinic. Additionally, the recent installation of an ABI automated DNA sequencer will enable sequence characterization of PCR amplified HIV patient samples.

In addition to civilian personnel reassignments of two positions to Molecular Biology, we suffered the loss of Ms. Kathy Lollar, our Med Tech, who moved back to her home state of Oklahoma in late September. In replacement of Ms. Lollar, the Department transferred Ms. Elaine Granata, previously working in the Microbiology Service, to assume clinical assay responsibility. Additional staffing losses of military personnel included the reassignment of SFC Dalton, Service NCOIC, in January and the appointment of SSG Stinnett to the position of Department NCOIC. Relief in the Service NCOIC position is anticipated in November.

The CDC guidelines, Preventing Lead Poisoning in Young Children, October 1991, continue to increase demand for pediatric blood determinations. At Fitzsimons, in conjunction with the Department of Pediatrics and the Exceptional Family Member Program, we have established a screening protocol directed at the FANC twelve month Well Baby Clinic population. Measurement of pediatric blood lead continues as a research protocol in examining Attention Deficit Hyperactivity Disorder and Developmental Delay in children at Madigan AMC.

In hemoglobin A_{1c} testing, the acquisition of a DIAMATTM, HPLC-based, automated hemoglobin analysis system, will alleviate some of the workload pressure from clinical tests. Correlation testing will be complete in early December, with conversion to the new method occurring at that time.

Protocol research has been productive through the year. Lab contributions to several protocols reached completion on studies related to bone resorption and calcium mobilization in response to long term, low-dose methotrexate therapy, effects of TRH on serum atrial natriuretic peptide, and cyclic nucleotide measurement. Current studies are examining acute phase protein response following laparoscopic surgery, red blood cell metabolism in the American Opossum, platelet thromboxane and aggregation and whole blood prostacyclin synthesis in human thyroid disease, and serum drug levels in support of a variety of protocols involving animal models.

Research conducted within the Service resulted in the recognition of two researchers. Dr. Michael O'Connell, Allergy and Immunology Service, was the recipient of the Hugh Mahon Lectureship Award for his studying effects of beta-adrenergic antagonists on intracellular cyclic nucleotide generation in guinea pig airway smooth muscle. Dr. Nicholas Bethlenfalvay, Outpatient Clinic, was the winner of the Federal Executive Board Annual Outstanding Scientist of the Year Award for his continuing work on red blood cell adenosine deaminase.

Collaborative arrangements with the University of Colorado Health Sciences Center have continued in support of the military physicians enrolled in the Neonatal Medicine Fellowship. In addition to ongoing amino acid analyses, pilot studies examining endocrine changes in response to hypoxia and intrauterine growth retardation in the fetal sheep model have begun this fall.

Improvements to the building continued through self help and contracted repairs. Notable improvements included new flooring and upgraded lighting in the main lab area, as well as renovated cabinetry and countertop workspace in the instrument lab. These improvements along with structural reinforcement of the second floor will finally allow installation of the GC/Mass Spectrometer obtained early last year from Letterman AMC. The general clean-up and repainting continue. This summer, through the efforts of Elise Sherva and the post Environmental Engineer, also saw final removal and disposal of the Department inventory of hazardous/outdated/unwanted chemicals and turn-in of the blockhouse facility.

In other areas, we initiated an in-service training program within the Service, and again this summer hosted two Barnard College students training in the Molecular Biology lab.

Cell Physiology Service - FY 92

COL Bennion of FPMC's Dermatology Service continued work using the athymic nude mouse to study the role of various factors (both internal and external) in the pathogenesis of the cutaneous lesions of Subacute Cutaneous Lupus Erythematosus (SCLE). Nude mice received human skin grafts in which factors can then be added and/or subtracted to investigate skin lesional disorders of SCLE. Rationale for this study was as follows: (1) Antibodies, specifically anti-nuclear antibodies, are found in lesions of cutaneous lupus. Thus, anti-Ro antibodies from a SCLE patient were injected into mice. (2) Skin lesions occur almost exclusively in sun-exposed areas, therefore mice were exposed to UVB light. (3) Mononuclear cell infiltrates are found in skin lesions and distinguish lesional from non-lesional skin. Consequently mononuclear cells were given. (4) Gamma interferon was injected into mice (it is believed that interferon increases ICAM-1 expression on keratinocytes, and therefore may provide an adhesion site for mononuclear cells which then produces tissue damage). It is these factors, the combination of all or some,

that may develop lesions which mimic SCLÉ. A total of 40 mice were grafted with human skin obtained from plastic surgery. 25 mice had evaluable human skin grafts, and many of the grafts were found with infiltrates. It is not presently known whether the infiltrates are human or mouse cells since the dye to determine this has not been received to stain the tissue. Mice demonstrating infiltrate involvement show good interaction with the epidermis. This pattern of staining is consistent with that of patients with SCLÉ. Thus, preliminary evidence indicates this may be a model for SCLÉ. The next set of experiments should help establish which of these components are necessary for the histologic changes to occur.

Dr. Bennion is also evaluating the diagnostic value of using monoclonal antibodies in identifying particular skin tumors or disorders. By altering culture conditions to mimic various pathologic environments, pre-confluent, cultured keratinocytes are utilized to simulate acantholytic round cell carcinoma and will be compared with post-confluent keratinocytes (normal state) for binding antigens, vimentin and cytokeratin. Data collection is in progress.

MAJ David-Bajar, also of Dermatology Service, has investigated procedures which may have potential use in diagnosing autoimmune type diseases. A split-skin technique, which separates the epidermis from the dermis of a collected skin specimen, when combined with immunofluorescence staining may improve current clinical methods for identifying certain blistering skin disorders such as herpes gestations, bullous pemphigoid, linear IgA dermatosis, and epidermolysis bullosa acquisita. In a related protocol, CPS is working with Dr. David-Bajar in processing serum samples for titer of anti-basement membrane zone antibodies and/or anti-intercellular substance antibodies sent from the Mayo Clinic's Immunofluorescence Laboratory. These efforts will allow FAMC to become a certified lab for indirect immunofluorescence testing.

Rheumatology fellow, Dr. Kim May, has collaborated with CPS personnel to successfully culture bone osteoblasts and osteoclasts. The bone cells are used to study the in vitro effects of low-dose methotrexate on bone physiology. Methotrexate, a widely used drug for treatment of rheumatoid arthritis, was previously demonstrated by Dr. May to cause osteopenia in rats. This study may provide important information into the prevention and treatment of methotrexate-induced osteoporosis.

Data was collected on 76 patients for MAJ Kopke study investigating the effects of smoking, alcohol ingestion and radiation treatment on Langerhans cells (LC's) in human oral mucosa. A much greater incidence of oral cavity cancers among smokers and chronic alcoholics has been reported in the medical literature. It is believed that these substances may alter the number and/or immune status of LC's, dendritic cells with

antitumor immunity, in oral mucosa. Immunohistochemical staining suggests that these substances may change LC populations from T-cell activators, tumor destroyers, to T-cell suppressor cells which promote tumor growth.

CPS is collaborating with the Neonatology departments of FAMC and UC Health Sciences Center in developing human and ovine placental trophoblast cultures to facilitate in vitro study of fetal metabolism. Phase I of this study has begun. Methodology for culturing normal human and ovine trophoblasts have been established through a series of studies on cultured choriocarcinoma cell lines. This investigation will provide further understanding about fetal growth and metabolism and may allow for development of possible interventions to effect improved placental function in different maternal disease states.

A CPS project has investigated the use of biological attachment factors for improvement of skin graft management and viability. Utilizing five groups of nude mice, four different attachment factors were compared against a control group. Preliminary data analysis suggests that certain attachment factors maintain a greater viable tissue area.

During FY 92, CPS collaborative efforts produced two scientific articles, two presentations and co-authorship of a book chapter. CPS trained four GME interns/residents, a fellow, and one medical student from UCHSC.

Clinical Biometrics and Research Design Service - FY 92

All Orthopedic and General Surgery residents now rotate through the Service as part of their regular training programs. During the rotation, they and a variety of other physicians learn clinical research design, clinical statistics, computer work and data processing as well as plan, write and initiate a research project. Formal courses have been presented in both research design and in techniques for self-regulation as part of pain management to physicians, psychologists, occupational therapists, and others. While research design support is still performed entirely within the Service, some of the support for statistical analysis is being performed through a grown set of BPAs.

During this fiscal year, the two major MRDC supported programs initiated two years ago were continued and broadened. The stress fracture treatment program has shown that stress reactions can be identified early enough to prevent progression to stress fractures and that stress fractures can frequently be treated successfully with the aid of electrical stimulation. The Service is now supported by HSC, MRDC, the VA, instrument manufacturers, and non-profit organizations.

The ambulatory recording - low back pain program centered among soldiers at Ft. Carson participating in combat exercises and among people local to Fitzsimons AMC has produced early

results demonstrating that low back pain frequently increases after low back muscle tension increases. Studies within the service have demonstrated that a large proportion of tension headaches occur only after an increase in shoulder muscle tension. Similar studies have demonstrated that cramping phantom pain only occurs after an increase in muscle tension in the residual limb. This fiscal year has also seen an increase in use of the new computer controlled tensile strength evaluation device for studies of bone and tendon healing as well as evaluation of the strength and resiliency of indwelling catheters.

Immunology Service - FY 92

The Immunology Service has continued to maintain its premiere position in a flow cytometry among military medical centers, with a high volume of work in lymphocyte immunophenotyping in HIV patients, leukemia and lymphoma typing, DNA and cell cycle analysis in breast cancers, and expanding work in the enumeration of lymphocyte subpopulations in immunodeficient and autoimmune patients. In addition, the past year has seen a large increase in work related to the functional analysis of immunocompetent cells, such as mitogen and antigen stimulated lymphocyte transformation assays, as well as flow cytometric studies of activation and "memory cell" markers on lymphocytes cultured from specific patients. Also, various immunochemical procedures such as electrophoresis and immunoblotting of antigens and antibodies ("Western blots") in specimens from autoimmune patients, enzyme-linked immunosorbent assays (ELISAs), radial immunodiffusion assays for immunoglobulin synthesized by cells cultured in vitro, immunochemical analysis of serum proteins by rate nephelometry, and peptide synthesis and sequence determinations have been performed. Finally, work continued on the research award winning protocols of Dr. Bethlenfalvai concerned with purine and pyrimidine metabolism in erythrocytes in adenosine deaminase deficiency (which is a cause of severe combined immunodeficiency-SCID).

Microbiology Service - FY 92

A multi-center HIV natural history study of antiretroviral resistance is providing information on the development of AZT resistance at the molecular level in HIV patients who are clinical treatment failures. The microbiology service is working with the Department of Diagnostic Retrovirology at WRAIR to analyze trends in the progression of HIV patients on long-term antiretroviral therapy.

Implementation of radiometric instrumentation in the mycobacteriology laboratory has permitted development of a study on synergy between antimycobacterial agents used for treatment of *M. avium* isolates from AIDS patients.

Methods for molecular epidemiology studies of clinical bacterial isolates are being evaluated. Plasmid analysis of

isolates re being evaluated. Plasmid analysis of isolates from the MICU and SICU is being performed to examine infection trends.

A study with the Allergy service has initiated comparing the efficacy of various extraction procedures for pollen allergens used in skin testing. We are supporting the Pulmonary service in a study of antimicrobial chemotherapy in bronchitis and pneumonia patients. This service has been providing western blot analysis in support of a protocol examining Hepatitis C therapy. A model of fungal sinusitis is currently being developed in collaboration with the Otolaryngology service.

Molecular Biology Service - FY 92

The Molecular Genetics Service DNA lab of Biochemistry Service. Dr. Anthony Gutierrez GS13, Ph.D. in Molecular Genetics, was designated the Chief and Ms. Judith O'Brien GS11, Medical Technologist/Chemist, is the Research Associate. These are the only assigned staff to the service. In addition to assigned staff the service took on three summer research interns. This was part of a program initiated last year by Dr. Gutierrez to give the service summer workers in return for biomedical research training. The interns were Ms. Allegra Cummings, a premed Biology major from Barnard College of Columbia University in New York City, Ms. Connie Chung, a premed Chemistry major from Cornell University in Ithaca, NY, and Ms. Stacie Moore, a student at The Community College of Aurora, CO. The service also benefited from the volunteer lab work of Mr. Scott Verrill, a sales manager of MicroBio Products, Inc. Mr. Verrill is working part time in the lab under the auspices of the Red Cross volunteer program to perform lab work in return for training. Neither interns nor volunteers receive any pay. The Service has also taken on long-term intradepartment training of other service personnel to include Mr. Rick Schlichtmeier GS9, and Sgt. Jeff Sipple, both of the Microbiology service.

The service was involved in several projects concerning the detection of pathogens and gene products by amplification and subsequent detection of their DNA from various patient samples. One major project involves the detection of incorporated HIV DNA in the peripheral mononuclear lymphocytes of patients. The service duplicated the WRAIR (Walter Reed Army Institute of Research) technique of using PCR (The Polymerase Chain Reaction) and radiolabelled probes to detect less than 10 infected cells in 300,000 from patient samples. The procedure was developed and optimized for this lab during the summer by Dr. Gutierrez, Ms O'Brien, Ms. Cummings and Mr. Schlichtmeier.

In March 1992 Dr. Gutierrez and Ms. O'Brien attended a 3-day course on applications of PCR technology at the Centers for Disease Control in Atlanta. They also met with Dr. Michael Beach of the Hepatitis Division at the CDC. Dr. Beach had provided us with invaluable assistance in adapting for our laboratory the CDC protocol for detection of hepatitis C virions in human serum

using reverse transcription and PCR. The information led to the optimization of the detection of HCV RNA in patient sera by Ms. O'Brien with technical assistance from Dr. Gutierrez and lab assistance from Ms. Chung. Dr. Kenneth Sherman investigated the possibility of quantitating HCV by PCR on serial dilutions of patients' sera, comparing our results to those obtained by a quantitative chemiluminescent procedure performed at the Chiron Corporation of Emeryville, California.

Maj. Homer Lamar, MD, LTC Bill Georgitis, MD, LTC Arnold Asp, MD and Maj. Greg Hughes, MD all from the Dept. of Endocrinology received training in molecular genetics to include DNA synthesis, PCR, Gel Electrophoresis, DNA radiolabelling and probe hybridization in an ongoing project involving the gene expression analysis of a putative thyroid tumor cell line. Mr. Verrill has been a central figure in this project. All training and supervision was provided by Dr. Gutierrez and Ms. O'Brien.

In October 1992 the Applied Biosystems automated DNA sequencer was installed and we began developing techniques and procedures for isolating and sequencing DNA. We were encouraged that our first attempt yielded the correct sequence for a fragment of the HCV genome. We are currently modifying our HIV PCR detection procedure to produce a Reverse Transcriptase gene fragment amenable to sequencing. This fragment putatively contains the mutations responsible for AZT resistance.

Lastly, during the year formal presentations were made on the training available at this Service to the fellows of the Dept. of Allergy and Immunology and the Dept of Dermatology by Dr. Gutierrez. The presentations included demonstrations of detection methodologies.

DEPARTMENT OF CLINICAL INVESTIGATION

ANIMAL RESOURCES SERVICE

Training Support Summary, FY 92

One Advanced Trauma Life Support (ATLS) exercise was conducted during the year, using four goats in the training of 16 staff physicians in the emergency management of casualties. 50-plus hours of training were provided, requiring 60 hours of support by Animal Resources Service personnel for planning, preparation, pre-op anesthesia induction, surgical preps, anesthesia monitoring, circulating, and cleanup.

Eight rats were utilized in support of microsurgery training in the re-anastomosis of small vessels, providing 75 hours of training for 2 staff surgeons from Plastic Surgery Service. Support of this training by Animal Resources Service personnel totalled nearly 60 hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and resterilization.

Thirty-six rats were used in support of microsurgery training in the re-anastomosis of small vessels, providing 600-plus hours of training for 2 staff surgeons and five residents from Orthopedic Surgery Service. Support of this training by Animal Resources Service personnel totalled nearly 200 hours, administering and monitoring anesthesia, surgical preps, cleanup, and instrument cleaning and resterilization.

Ten enlisted members of Emergency Medicine Service, in MOS 91A, 91B, or 91C, were trained in suturing techniques. Training consisted of an overview of operating room procedure, including aseptic technique, operating room rules of etiquette, instruction in the surgical hand scrub, and gowning and gloving, and hands-on experience in dry and wet labs. Training was conducted on one day and utilized ten rats. Forty-plus hours of training were received, requiring sixty-plus hours of support by Animal Resources Service personnel.

One exercise was conducted in "Resuscitation of Newborn" for the American College of Obstetricians and Gynecologists/Indian Health Service Postgraduate Course in Obstetrics, Gynecology and Neonatology. Over one hundred physicians, nurse practitioners, and midwives received 165 hours of training in methods of resuscitation and endotracheal intubation, using 17 ferrets and requiring nearly 100 hours of support by Animal Resources Service personnel. The ferrets were recovered and returned to the colony for re-use.

Thirty-eight physician and paramedical personnel received 114

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PUBLICATIONS & PRESENTATIONS

FY 92

PUBLICATIONS

C = Protocol Related

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C Perloff JJ: The effects of thyroid hormone suppression and calcitonin deficiency on bone mass. Presented. The Endocrine Society, San Antonio, TX 1992.

Sample SA: A case of multicentric castleman's disease and kaposi's sarcoma. Presented: Army Am Coll Physicians, October 1991.

Spaulding HS: Summary report of general allergic diseases encountered in the Persian Gulf theater of operations. Presented: Am Coll All/Imm, New York, NY, November 1991.

Tell DT et al: Crystalline keratopathy in smoldering myeloma. Presented and Published: 9th Army Regional Meeting, 1992.

West SG: Is a rheumatologist of any value in a military combat zone? Presented and Published: ACR meeting, Arth Rheum 34:191, Boston, MA November 1991.

DEPARTMENT OF CLINICAL INVESTIGATION

Banks RE: A discussion of the animal rights movement for the military veterinarian. Presented: Western States Military Veterinary Symposium, San Antonio, TX 1992.

C Blakeslee DB et al: Correlation of the vocal fold vibratory pattern with the post-operative surgical wound in the miniswine model. Presented: Acad Surg Resch, Chicago, IL 1992.

C Sherman KE et al: Serologic and genomic markers of viral hepatitis in patients with HIV infection. Presented: Digestive Dis Week, Am Gastro Assoc, San Francisco, CA, May 1992.

C Sherman RA: Pain and the problem causing it aren't always in the same place. Presented: The Assoc for Applied Psychophysiology, Colorado Springs, CO 1992.

DEPARTMENT OF OB-GYN

Fisk DR et al: Low grade squamous intraepithelial lesions: Are they all the same? Presented: Am Soc for Colposcopy and Cervical Pathology 1992 Biennial, Orlando, FL 1992.

DEPARTMENT OF PATHOLOGY

C Butler CE et al: Evaluation of the DNA probe direct test of rN. gonorrhoea on treated patients. Presented: Am Soc Microbiology, New Orleans, LA 1992.

DEPARTMENT OF PEDIATRICS

C Burgess DB et al: Developmental screening in the military. Presented: Santa Fe, NM 1992.

Carter BS: Cardiac hypertrophy and disproportionate septal hypertrophy in newborns with hyperinsulinism. Presented and Published: Clinical Research 40:19A, 1992.

Moore RR: Glutamate flux between placenta and fetus: Magnitude and potential significance. Presented and Published: Pediatric Research 31:48 A, 1992.

DEPARTMENT OF SURGERY

Beck WG et al: A further examination of the speech intelligibility (SIR) test. Presented: Am Speech-Language Hearing Assoc, Atlanta, GA, November 1991.

Bray VJ et al: Hydroxychloroquine toxicity and efficacy in rheumatic disease. Presented and Published: Arthritis Rheu 35:R25, 1992.

Brown CW et al: The natural history of thoracic disc herniation. Presented: Soc Military Ortho Surgeon, Colorado Springs, CO 1992.

C Callahan B: Effect of coumadin on fixation of hydroxyapatite-coated and uncoated porous Co-Cr-Mo alloy implants in a goat model. Presented and Published: Orthopaedic Transaction, 16(3), Fall 1992.

C Callahan B: Effect of coumadin on fixation of hydroxyapatite-coated and uncoated porous Co-Cr-Mo alloy implants in a goat model. Presented and Published: J Invest Surgery 5(3), 1992. SOMOS, El Paso, TX, November 1991

C Callahan B et al: Attachment of Ha-coated and uncoated porous implants is influenced by coumadin. Presented: Acad Surg Resch, Chicago, IL 1992.

C Callahan B et al: Attachment of Ha-coated and uncoated porous implants is influenced by coumadin. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

C Callahan B et al: Attachment of Ha-coated and uncoated porous implants is influenced by coumadin. Presented: Smith & Nephew Richards 10th Annual Residents Conf, Memphis, TN 1992.

C Callahan B et al: Attachment of Ha-coated and uncoated porous implants is influenced by coumadin. Presented: Am Acad Ortho Surg, San Francisco, CA 1992.

C Callahan et al: Effect of nicotine on bone ingrowth and fixation in hydroxyapatite coated and uncoated porous Co-Cr-Mo alloy implants in a goat model. Presented: Reconstruction Surgery of the hip and Knee Course, Durango, CO 1992.

Coe R: Limb-sparing surgery for soft tissue sarcomas below the knee. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992, Am Ortho Assoc Residents Conf, Ann Arbor, MI 1992.

Coe R: Limb-sparing surgery for soft tissue sarcomas below the knee. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992, Am Ortho Assoc Residents Conf, Ann Arbor, MI 1992.

Coe R: Occipitocervical instability in Down Syndrome. Presented and Published: Soc Milt Ortho Surgeons, Colorado Springs, CO 1992.

Coe RA et al: The SROM Femoral prosthesis: Is modularity self defeating? Presented: Barnard Competition, Denver, CO 1992.

Cope EE: Triple injection arthrogram with rapid sequence 105 mm x-ray: Presentation of a new technique. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992, Am Acad Ortho Surgeon, Washington, DC 1992.

Cope EE: Tarsal coalition: The children's hospital experience. Presented: Barnard Competition, Denver, CO 1992

Cope EE: Tarsal coalition: The children's hospital experience. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992

Deffer P et al: Congenital pseudarthrosis of the clavicle. Presented: Western Ortho Assoc, Monterey, CA 1992.

Deffer PA et al: Clavicle fractures in the newborn: Fracture versus pseudarthrosis. Presented: Barnard Competition, Denver, CO 1992.

Deffer PA et al: Clavicle fractures in the newborn: Fracture vs pseudarthrosis. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

Enzenauer RW et al: Treatment of scleromalacia perforans (SP) with dura matter (DM) grafting. Presented and Published: Arthritis Rheu 35:R24, 1992.

Enzenauer RW et al: Radial keratotomy in the soldier-aviator. Presented: Aerospace Med Assoc, Miami, FL 1992.

Eusterman VE et al: Gelfilm barrier for prevention of post-parotidectomy Frey's syndrome: A human and animal model experience. Presented: Annual AAO-HNS meeting, Washington, DC 1992.

Farber G et al: Tibial nonunion treated with ilizarov. Presented: Barnard Competition, Denver, CO 1992.

Farber G et al: Analysis of instrumented spine fusion with emphasis on complications and use of radiographs for screw placement. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

Friedel S et al: Avascular necrosis of the metatarsal heal following chevron osteotomy: An evaluation by MRI. Presented: Barnard Competition, Denver, CO 1992.

C Gillogly SD et al: The accuracy of magnetic resonance imaging in assessment of patellar tendon autograft anterior cruciate ligament reconstruction. Presented: Barnard Competition, Denver, CO 1992.

Heier J et al: Ocular injuries at a CSH in support of operations desert shield and storm. Presented: ARVO annual meeting, Sarasota, FL, 1992.

C Jones DEC et al; Efficacy of percutaneous trigger finger release: An anatomic study. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

Lisecki E et al: Hip lesions mimicking primary osteoarthritis, A radiographic and histopathologic study. Presented: Am Acad Ortho Surg, San Francisco, Ca 1992.

C Liescki E et al; Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by methotrexate and coumadin. Presented: Controversies in Total Joint Arthroplasty, 1st Annual fall Retreat. Milwaukee, WI, 1992.

C Liescki E et al; Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by methotrexate and coumadin. Presented: Reconstruction Surgery of the Hip and Knee Course, Durango, CO 1992.

C Liescki E et al; Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by methotrexate and coumadin. Presented: Hips and Chips, Castle Rock, CO 1992.

C Lisecki EJ et al: Experimental and clinical results of hydroxyapatite-coated total hip replacements. Presented: Hips and Chips, Castle Rock, CO 1992.

C Lisecki EJ et al: Experimental and clinical results of hydroxyapatite-coated total hip replacements. Presented: Ortho Resch Soc, San Francisco, CA 1992.

C Lisecki EJ et al: Experimental and clinical results of hydroxyapatite-coated total hip replacements. Presented: Controversies in Total Joint Arthroplasty, 1st Annual fall Retreat, Milwaukee, WI 1992.

C Liescki E et al; Attachment of hydroxyapatite-coated and uncoated porous implants is influenced by methotrexate and coumadin. Presented: Ortho Resch Soc, San Francisco, CA 1992.

C Lisecki EJ: Randomized, prospective clinical evaluation of HA-coated and non HA-coated porous total hip replacements by a single surgeon. Presented: Am Acad Ortho Surg, San Francisco, Ca 1992.

C Lisecki EJ: Randomized, prospective clinical evaluation of HA-coated and non HA-coated porous total hip replacements by a single surgeon. Presented: Controversies in Total Joint Arthroplasty, 1st Annual Fall Retreat, Milwaukee, WI 1992.

C McBride et al: Biomechanical analysis of central one-third patellar ligament defects in a New Zealand rabbit model. Presented: Soc Milt Ortho Surg, Colorado Springs, C 1992.

C Pals S et al: Biomechanical evaluation of the goat patellar tendon after harvest of its middle third. Presented: Am Acad Ortho Surg, San Francisco, Ca 1992.

C Pals S et al: Biomechanical evaluation of the goat patellar tendon after harvest of its middle third. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

C Pals S et al: Evaluation of the goat patellar tendon after harvest of its middle third. Presented: Am Ortho Assoc, Ann Arbor, MI 1992.

C Pals S et al: Evaluation of the goat patellar tendon after harvest of its middle third. Presented: Barnard Competition, Denver, CO 1992.

C Pals S: Patellar tendon healing and strength following patellar tendon autograft harvest in goats. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992.

Place H et al: Stabilization of thoracic spine fractures resulting in complete paralysis: A long-term retrospective analysis. Presented: Soc Milt Ortho Surg, Colorado Springs, CO

Reister J et al: Carpal ligamentous injuries associated with fractures of the distal radius. Presented: Barnard Competition, Denver, CO 1992.

Schaefer RA et al; Musculoaponeurotic fibromatosis (extra-abdominal desmoid tumors): A protocol for treatment. Presented: Am Ortho Residents Conf, Ann Arbor, MI 1992.

Schaefer R: Radiographic analysis of patellar height after ACL reconstruction. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992.

Spezia PM et al: Femur fractures in alpine skiers. Presented: Am Fracture Assoc Essay Contest, Orlando, FL 1992.

C Spezia P: Nonsurgical treatment of Morton's neuroma with local injection of B-12/solomedrol/lidocaine combination. Presented and Published: Orthopaedic Transactions 16(3), Fall 1992.

Spezia PM et al: Femur fractures in alpine skiers. Presented: Ass Milt Osto Phys and Surg, Scottsdale, AZ 1992.

Spezia PM et al: Femur fractures in alpine skiers. Presented: Western Ortho Assoc, Monterey, CA 1992.

Spezia PM et al: Femur fractures in alpine skiers. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

Spezia PM et al: External fixation of pediatric femur fractures. Presented: Western Ortho Assoc, Monterey, CA 1992.

Spezia PM et al: External fixation of pediatric femur fractures The Children's Hospital Experience. Presented: Barnard Competition, Denver, CO 1992.

Spezia P et al: External fixation of pediatric femur fractures versus 90-90 skeletal pin traction: Cost and effectiveness. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

C Whitecloud T III et al: Experimental and clinical results with hydroxylapatite-coated total hip replacement. Presented: 9th Meeting Ortho Assoc English-Speaking World, Toronto, Canada 1992.

C Whitecloud T III et al: Randomized prospective clinical evaluations of hydroxylapatite-coated and non-hydroxylapatite coated porous total hip replacements. Presented: Clin Ortho Soc, Denver, CO 1992.

C Wolff J et al: Effects of methotrexate on bony ingrowth in hydroxyapatite coated and uncoated porous implants in a goat model. Presented: Am Ortho Assoc, Seattle, WA 1992.

C Wolff J et al: Effects of methotrexate on bony ingrowth in hydroxyapatite coated and uncoated porous implants in a goat model. Presented: Soc Milt Ortho Surg, Colorado Springs, CO 1992.

Yoshida GY: Laryngeal chondronecrosis and malignant neuroendocrine tumor of the head and neck. Presented: Pacific Coast oto-ophthalmological Society, Waiakaloa, HI, June 1992.

Yoshida GY: Malignant neuroendocrine tumor of the frontal sinus and temporal bone. Presented: Annual AAO-HNS meeting, Washington, DC 1992.

DEPARTMENT OF RADIOLOGY

Heironimus JD et al: Clinical correlation of bilateral slanthole tomography for cardiac scintigraphy. Presented and Published: Clin Nucl Med 17(3):256, 1992.

Heironimus JD et al: A comparison of exercise and adenosine Tc-99m sestamibi myocardial scintigraphy in patients with left bundle branch block. Presented and Published: Clin Nucl Med 17(3):256, 1992.

McDevitt GR et al: Sensitivity and specificity of malignant pleural effusion and bone scintigraphy. Presented and Published: Clin Nucl Med 17(3):254, 1992.

Toney MO et al: Gastric emptying : Solid-phase geometric means analysis in dynamic imaging. Presented and Published: Clin Nucl Med 17(3):255, 1992.

Wyatt RA et al: Bone mineral density in young adult females with lower extremity pain. Presented & Published: Clin Nucl Med 17(3):252, 1992.

Wyatt RA et al: Tc-99m human serum albumin and protein losing enteropathy: A case report and review of the literature. Presented and Published: Clin Nucl Med 17(3):257, 1992.

DETAIL SUMMARY SHEETS

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/120 (3) Status: Ongoing

(4) Title: Evaluation of Carbohydrate Metabolism in Thyrotoxicosis:
Investigations into the Frequency, Type and Mechanisms
of Carbohydrate Tolerance

(5) Start Date: 1981

(6) Est Compl Date: 1991

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators:

(11) Key Words:
carbohydrate
hyperthyroidism

Fred D. Hofeldt, COL, (Ret)
Robert J. Sjoberg, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The first objective of the study is to determine the frequency and reversibility of carbohydrate intolerance in thyrotoxicosis and to determine the importance of gut factors by doing oral and intravenous glucose tolerance test. The second objective is to study the mechanisms of carbohydrate intolerance. This objective will be approached by measuring glucose, insulin, glucagon and free fatty acids, basally and after oral intravenous glucose and by measuring the responses to exogenous insulin.

(16) Technical Approach: Ten non-diabetic patients who are taking no medications, are less than age 45, are less than 120% of ideal body weight, will be studied while thyrotoxic and after recovery. Each

CONTINUATION SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol #: 80/120

patient will have an oral and an intravenous glucose tolerance test. Each patient will have an insulin tolerance test basally and following glucose infusion.

(17) Progress: No patients have been enrolled in this study during the past academic year. The research study is still entirely valid and worthwhile in purpose. The principal investigator has not had adequate time to pursue this project as it is very complex. However, it is still hoped that a new Endocrine Fellow will pick up this project and complete it within the next year to a year and a half. A tremendous amount of effort has already been expended on this study, and it is requested that the protocol be continued in hopes of mobilizing associate investigators to pursue the project. FY 91, no progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 81/117 (3) Status: Ongoing

(4) Title: The Role of Calcitonin in Osteoporosis

(5) Start Date: Reactivate 1987 (6) Est Compl Date:

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators: Gerald S. Kidd, COL, MC

(11) Key Words:
osteoporosis
bone density
calcitonin deficiency
thyroid hormone

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: ongoing
c. Number of Subjects Enrolled During Reporting Period: 5
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if, longitudinally, thyroid cancer patients who have calcitonin deficiency and are on suppressive doses of thyroid hormone, loose radial bone more rapidly than goiter patients, who are also on suppressive doses of thyroid hormone but are not calcitonin deficient, and than normal controls. Also to compare these 3 groups, cross-sectionally, for bone density of the spine and hip.

(16) Technical Approach: 3 Groups: (a) thyroid cancer patients - calcitonin deficient and on thyroid hormone; (b) goiter patients - not calcitonin deficient but are on thyroid hormone, and (b) normal controls. (SPA) single photon absorptiometry-distal and midradius serially for 5-6 yrs (in progress since 1981) (DPA) dual photon absorptiometry - spinal & hip- cross-sectionally.

(17) Progress: Total number of patients enrolled to date: 44 cancer, 99 goiter, and 100 normal. All data have not yet been collected and analyzed. Preliminary analysis will be presented. Cross sectional study shows that goiter patients have lower bone density in the spine, mid-radius and distal radius compared to controls while thyroid cancer patients were lower at the mid-radius and distal radius but not the spine. Longitudinal study reveals a greater rate of bone loss in goiter and thyroid cancer patients than in controls but the difference is significant only in goiter patients. Power analysis indicates that obtaining followup data on more of the thyroid cancer patients, which is underway, will be necessary to avoid a Type II error.

Publications:

McDermott MT, Kidd GS, Blue P, Ghaed V, Hofeldt FD: Reduced bone mineral content in totally thyroidectomized patients: Possible effect of calcitonin deficiency. J Clin Endocrinol. Metab 56:936-9, 1983.

McDermott MT, Hofeldt F, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. J Bone Min Res (1(suppl. 1):352, 1986 (Abstract).

Presentations:

McDermott MT, Hofeldt FD, Kidd GS: Calcitonin deficiency does not affect the rate of radial bone loss. Presented: 8th Annual Scientific Meeting, American Society for Bone and Mineral Research, Anaheim, CA 1986.

Perloff JJ, McDermott MT, Damiano MA, Kidd GS: The effects of thyroid hormone suppression and calcitonin deficiency on bone mass. 74th meeting of the Endocrine Society, San Antonio, TX, June 1992.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 81/118 (3) Status: Ongoing

(4) Title: Hypothalamic Pituitary Gonadal Function in Hypothyroidism

(5) Start Date: 1981

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:
Gerald S. Kidd, LTC, MC

(11) Key Words:
hypothyroidism
gonadal dysgenesis
gonadotropins, pituitary

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV___ b. Review Results:___
c. Number of Subjects Enrolled During Reporting Period:___
d. Total Number of Subjects Enrolled to Date: 1___
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The objectives of this protocol are to define more clearly the mechanisms of gonadal dysfunction occurring in hypothyroidism and to see if these abnormalities resolve after treatment of the hypothyroid state.

(16) Technical Approach: A prospective study to assess in a pair manner results of alterations in HPG axis as a consequence of hypothyroidism when evaluated with GnRH infusion and TRH testing, clinical stimulation and HCG testing in males and females.

(17) Progress: No progress in the past year.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 83/122 (3) Status: Completed

(4) Title: The Role of Food Allergy in the Pathogenesis of Migraine Headaches

(5) Start Date: 1983

(6) Est Compl Date: 1992

(7) Principal Investigator:
Thurman R. Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators:

(11) Key Words:
migraine
food hypersensitivity

David L. Goodman, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____12_____
d. Total Number of Subjects Enrolled to Date:_____104 completed program.
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To study the value of allergy food skin test in directing and defining a diet which will cause a decrease in the frequency of migraine headaches in affected patients.

(16) Technical Approach: Approximately 100 patients with dx of migraine headaches who suffered 3 or more HA/month will keep a 1 month food diary/st diary. They will then be skin tested to 83 common foods and undergo an additional 1 mo diet eliminating suspected food, and skin test positive foods. Positive regimens will be studied with open chall. and double blind food challenge with immunologic mediators precursors.

(17) Progress: Study completed FY 92.

Presentations:

(1) Vaughan, TR, Stafford, WW, Miller, BT, Weber, RW, Tipton, WR, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: American College of Allergists, Phoenix, AZ, January 1986.

(2) Vaughan, TR, Stafford, WW, Miller, BT, Tipton, WR, Weber, RW, Nelson, HS: Food and Migraine Headache: A Controlled Study. Presented: Aspen Allergy Conference, Aspen, CO, July 1986.

CONTINUATION SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol # 83/122

(3) Vaughan TR, Stafford WW, Miller BT, Tipton WR, Weber RW, Nelson HS: Food and Migraine Headache: A Controlled Study. Presented: Southwest Allergy Forum, El Paso, TX, March 1987.

(4) Kossoy AF, Vaughan TR, Stafford WW, Miller BT, Nelson HS, Weber RW: Food and Migraine Headache: A Double-Blind, Long-term Followup Study. Presented: VI International Food Allergy Symposium, Boston, MA., November 1987.

(5) Vaughan TR: Food and Migraine Headache. Presented: Keystone Allergy Conference, Keystone, CO., February 1988.

Publications:

1. Stafford WM, Weber RW, Vaughan TR. The Role of Food in Migraine Headache. Am J Asthma Allergy, 3:143-152, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 83/126 (3) Status: Ongoing

(4) Title: The Role of Altered Prostaglandin Synthesis in the Impaired Water Excretion and Abnormal Renin-Aldosterone Axis of Hypothyroidism

(5) Start Date: 1983

(6) Est Compl Date: 1992

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/ Endocrine

(10) Associate Investigators:

(11) Key Words:
prostaglandin synthetic
hypothyroidism
water electrolyte balance, imbalance

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to determine in an indirect manner i.e., with prostaglandin synthesis inhibition, if the abnormal suppressibility of vasopressin and/or altered renal sensitivity to vasopressin seen in hypothyroid patients is caused by altered prostaglandin levels. This will be done by measuring serum vasopressin levels and urinary water excretion in response to a water load, as well as the renal response to exogenous vasopressin, in hypothyroid patients with and without prostaglandin synthesis inhibition, both before and after treatment with thyroid hormone to the point of euthyroidism. In the same way, the influence of altered prostaglandin levels on the renin-aldosterone axis of hypothyroidism will be studied by measuring plasma renin activity and aldosterone levels in these patients while in

CONTINUATION SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol #: 83/126

a relatively volume depleted state, that is before the water loading is performed. Altered renal prostaglandin synthesis in hypothyroidism will also be assessed directly by measuring urinary PGE-2 excretion in the hypothyroid and euthyroid states. (Urinary PGE-2 excretion is thought to reflect primarily renal PGE-2 production.)

(16) Technical Approach: By measuring urinary prostaglandin E and water loading responses in hypothyroid patients before and after indomethacin administration as well as measuring plasma, aldosterone, and plasma renin activity we will evaluate the effects of prostaglandin synthesis inhibition on water metabolism.

(17) Progress: Because of competing priorities, no subjects have yet been studied. A new fellow will be assigned to complete the study, protocol is still worthwhile and should be continued.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 84/119 (3) Status: Ongoing

(4) Title: Treatment of Graves' Ophthalmopathy with Cyclosporin

(5) Start Date: 1984

(6) Est Compl Date: 1992

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Leonard Wartofsky, COL, MC

(8) Facility: FAMC
WRAMC
MAMC
BAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Anthony Truxal, CPT, MC

(11) Key Words:
eye disease
cyclosporin
prednisone

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Cyclosporinte - Acne (1 pt.) Prednisone - Acne, swelling (1 pt.) Arthralgia on withdrawal (1 pt.)

(15) Study Objective: To determine the effectiveness of cyclosporin in the treatment of Graves' eye disease.

(16) Technical Approach: Patients with Graves' eye disease will receive a 3-week course of cyclosporine or prednisone, then have a 3-week rest. Then, 3 weeks of prednisone or cyclosporine (crossover). They will be followed by complete eye examination and CT scan of the orbits before and after each drug period, and twice weekly with CBC, SMA-18, urinalysis and B-2 microglobulin (urine).

(17) Progress: No new patients enlisted from FAMC in the past year. Two patients added from other medical centers. Results in patients evaluated thus far as a group are kept at Walter Reed and have not yet been analyzed. FY 91, no progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 85/100 (3) Status: Completed

(4) Title: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs. Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III
SWOG #7804

(5) Start Date: 1978 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Study is closed, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 85/139 (3) Status: Ongoing

(4) Title: National Intergroup Protocol for Intermediate Thickness
Melanoma 1.0-4.0 mm. Evaluation of Optimal Surgical Margins
(2 vs 4 cm) Around the Primary Melanoma and Evaluation
of Elective Regional Lymph Node Dissection
SWOG #8393

(5) Start Date: 1983 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 85/167 (3) Status: Ongoing

(4) Title: The Effect of Age on Thyroid Function Studies: The Perchlorate Discharge Test

(5) Start Date: 1985

(6) Est Compl Date: 1992

(7) Principal Investigator:
Gerald S. Kidd, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators

(11) Key Words:
thyroid diseases
thyroid function tests
thyroid gland

William J. Georgitis, MAJ, MC
Michael T. McDermott, MAJ, MC
Peter Blue, LTC, MC
Stephen M. Manier, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the effect of age on the perchlorate discharge test in individuals with thyroid disease.

(16) Technical Approach: Patients over the age of 60 years without thyroid disease by history, physical examination and lab evaluation will be studied. A perchlorate test will be performed in Nuclear Medicine.

(17) Progress: No progress has been made due to inadequate time of principal investigator; however, the study is thought to still be valid and worthwhile. A new Endocrine Fellow will pick up this protocol and complete it. No progress in FY92. An addendum is needed to add a control group.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 86/109 (3) Status: Terminated

(4) Title: The Effect of INH and Combination INH-Rifampin Therapy on Calcium and Vitamin D Metabolism

(5) Start Date: 1986

(6) Est Compl Date: 1991

(7) Principal Investigator:
John Merenich, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Gerald S. Kidd, LTC, MC
Michael E. Perry, COL, MC
Michael T. McDermott, MAJ, MC
Fred Negron, CPT, MC
Peter Blue, LTC, MC
Arnold Asp, MAJ, MC

(11) Key Words:
calcium
vitamin D rifampin
vitamin D deficiency

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: The purpose of this study is to see if INH therapy alters vitamin D and/or calcium metabolism in a significant manner. This may then lead to further evaluation to determine if patients would benefit from vit D or calcium supplementation while receiving INH therapy.

(16) Technical Approach: Ten to 20 patients will be begun on INH therapy for their recent PPD conversion. Determinations of Vit D (25-OH, 1,25-OH), serum calcium, PTH, 24-hour urine calcium and SMA-18 are drawn at baseline, 2 weeks, 6 and 9 months. Bone densitometry is obtained before and after therapy.

(17) Progress: Seven patients were enrolled but no followup was accomplished. Data was incomplete due to multiple investigators and transfers there of study was not feasible.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 86/114 (3) Status: Ongoing

(4) Title: Natural History of HIV 1 Infection and Disease in a
United States Military Community

(5) Start Date: 1986

(6) Est Compl Date: 1992

(7) Principal Investigator:
Gates, Robert H. LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators
Richard Harris, LTC, MS

(11) Key Words:
HIV virus

Roland N. Hannon, PA-C, CW3(RET)
Jefferey Casserly, PA-C, CW3(RET)
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jan 91 b. Review Results: Ongoing

c. Number of Subjects Enrolled During Reporting Period: 60

d. Total Number of Subjects Enrolled to Date: 600

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To develop an accurate, thorough understanding of the pattern of disease progression and clinical course in individuals with documented HIV infection within the general military population including active duty, dependents, and retirees. This will provide critical information for clinical and administrative management of patients.

(16) Technical Approach: Collect data on all patients who are required to be staged by DA directives and any who request staging.

(17) Progress: No changes except as noted for amendments in the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 86/120 (3) Status: Completed

(4) Title: A Phase II Comparison of CHOP versus m-BACOD versus
ProMaCE-CytaBOM versus MACOP-B in Patients with
Intermediate or High Grade Non-Hodgkin's Lymphoma
SWOG #8516

(5) Start Date: 1986 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group in the study of
adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/103 (3) Status: Completed

(4) Title: Identification of Those at Risk for Osteoporotic Fractures
by a Non-Invasive Measurement

(5) Start Date: 1987

(6) Est Compl Date: June 1990

(7) Principal Investigator:
Michael T. McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators
Gerald Kidd, COL, MC

(11) Key Words:
osteoporosis
hip fractures

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 25
d. Total Number of Subjects Enrolled to Date: 70
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To evaluate possible risk factors for osteoporosis
by comparing hip fracture patients and matched controls for bone
density, calcium intake, smoking, medications, mental status, visual
acuity, vitamin D levels and exercise history.

(16) Technical Approach: Hip fracture patients, within 5 days of
fracture, and normal matched controls will have measurement of bone
density at 3 sites in the unaffected hip and in the spine by dual photon
absorptiometry and in the non-dominant midradius by single photon

absorptiometry. All subjects will have a history and physical examination to include dietary and exercise history. Twenty subjects from each group will have visual acuity and 25-hydroxy vitamin D levels evaluated.

(17) Progress: Patients with hip fractures had significantly reduced bone density in the hip and lumbar spine and significantly lower calcium intakes. No further progress. The manuscript has been submitted for publication.

Presentations:

(1) McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. Presented: 10th Annual Scientific Meeting, American Society for Bone and Mineral Research, New Orleans, La, 1988.

Publications:

(1) Perloff JJ, McDermott MT, Perloff KG, Kidd GS: Risk factors for osteoporotic hip fractures. J Bone Min Res 3(Suppl. 1):587(73A), 1988, (Abstract).

(2) Perloff JJ, McDermott MT, Perloff KG, Blue PW, Enzenhauer R, Seik E, Chantelois A, Dolbow A, Kidd GS: Risk factors for osteoporotic hip fractures (Submitted for publication).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/104 (3) Status: Completed

(4) Title: A Randomized Investigation of High-Dose Versus Standard
Dose Cytosine Abarinoside with Daunorubicin in Patients
with Acute Non-Lymphocytic Leukemia, Phase III
SWOG 8600

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: One patient enrolled; patient failed 2 courses of
induction therapy; disease progressed and patient died.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/112 (3) Status: Completed

(4) Title: (RTOG-85-01) Prospective Trial for Localized Cancer of The
Esophagus: Comparing Radiation as a Single Modality to the
Combination of Radiation Therapy and Chemotherapy, Phase
III Intergroup
SWOG-8598

(5) Start Date: (6) Est Compl Date: 1990

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the SWOG group
in the study of adult oncological malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/114 (3) Status: Ongoing

(4) Title: Patient Evaluation of Physicians' Humanistic Qualities

(5) Start Date:

(6) Est Compl Date: 1992

(7) Principal Investigator:
Michael J. Weaver, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Gen. Med Svc.

(10) Associate Investigators

Cathy L. Ow, CPT, MC

(11) Key Words:
humanistic qualities
medical residents

Debbie Walker, LTC, AN

Ernest Degenhardt, MAJ, AN

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a) to determine what behaviors are considered by patients to be important markers of humanistic qualities in their physicians; b) to develop and test a questionnaire for a patient to rate the humanistic qualities of their own physician, and (c) to determine whether feedback, based on their own patients' ratings, can result in a change in physicians' humanistic behaviors.

(16) Technical Approach: The study consists of three phases: (a) open-ended interviews with patients to elicit important physicians' humanistic behaviors; (b) development and testing of a questionnaire from the responses generated in Phase a, and (c) we will give back feedback to physicians, based on their own patients' evaluation of their humanistic behaviors, using the questionnaire developed, and measure whether there is any change on a repeat questionnaire, post-feedback.

(17) Progress: Data analysis completed for 2nd version of questionnaire. Manuscript reporting results of 1st and 2nd phases is in preparation. 3rd phase will begin in fall of 1992.

Publications:

Weaver MJ, Ow CL, Walker DJ and Degenhardt EF: Evaluation of Residents Humanistic Qualities by Patients and Attending Physicians (Abstract Submitted)

Presentations:

Ow C, Weaver M, Walker D, Degenhardt E: Patient Evaluation of Physicians Humanistic Qualities. (Accepted for presentation at Army Regional LAP meeting, October 1989).

Weaver MJ, Ow CL, Walker DJ, Degenhardt EF: Evaluation of resident's humanistic qualities by patients and attending physicians. Presented at 5th Biennial Symposium for Teaching Internal Medicine, Boston, MA Nov. 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 87/116 (3) Status: Ongoing
-
- (4) Title: Effect of Iodine Containing Water Purification Tablets
on Thyroid Function in Man
-
- (5) Start Date: Aug 87 (6) Est Compl Date:
-
- (7) Principal Investigator: Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Endocrinology (10) Associate Investigators
John R. Barrett, LTC, MC
William J. Georgitis, LTC, MC
Robert J. Sjoberg, MAJ, MC
John A. Merenich, CPT, MC
Kenneth Simcic, CPT, MC
-
- (11) Key Words:
iodine
water purification tablets
thyroid function tests
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: AUGUST b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".
-
- (15) Study Objective: The objectives of this study are to investigate
the effects of iodine containing water purification tablets on thyroid
function and job performance in soldiers in a field environment.
-
- (16) Technical Approach: See Protocol
-
- (17) Progress: No progress has been since last FY. The manuscript has
been submitted for publication and the reviewers have asked that we
measure serum iodine levels. We have been working with Biochemistry
Service, DCI, since then to try to develop an assay for serum iodine but
have so far been unsuccessful. Alternately we may eventually send them
to a commercial lab. We are still trying to get serum iodide
measurements.
- Presentations:** Georgitis WJ, McDermott MT: Iodide water purification
tablets alter thyroid function in man. Presented: 71st Meeting of the
Endocrine Society, Seattle, WA. Endocrinology 124(Suppl):480 (1830A),
1989.
- Publications:** None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 88/109 (3) Status: Completed

(4) Title: Methotrexate in the Treatment of Steroid Dependent
Asthmatics

(5) Start Date: 1989

(6) Est Compl Date: 1992

(7) Principal Investigator:
Thurman R. Vaughan, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc.

(10) Associate Investigators

(11) Key Words:
asthma, steroid dependent
methotrexate

David L. Goodman, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APRIL b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 2

d. Total Number of Subjects Enrolled to Date: 17

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the effectiveness of weekly methotrexate in reducing the steroid requirements of steroid dependent asthmatics. The purpose is to demonstrate a statically significant reduction in the steroid dose over the placebo control, without involvement of the other parameters.

(16) Technical Approach: Double blind crossover design with methotrexate and placebo following pulmonary function tests, symptom scores with attempt to taper corticosteroids.

(17) Progress: Fifteen patients have completed the study, and ten have benefited judged by increase in PFTs and decrease in total steroid use.

Presentations:

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Harold S. Nelson Symposium, FAMC, Feb 89.

CONTINUATIONS SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol #: 88/109

Dyer PD, Vaughan TR, Weber RW: Methotrexate in the treatment of steroid dependent asthmatics. Presented: Aspen Allergy Conference, Aspen, CO July 1989.

American College of Allergy & Immunology Annual Scientific Meeting, Orlando, FL, Nov, 89.

Publications:

(1) Dyer PD, Vaughan TR, Weber RW: Methotrexate in the Treatment of Steroid Requiring Asthma. J All Clin Immunol (April) 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/112 (3) Status: Terminated

(4) Title: Long-Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer. Phase II Pilot Study

(5) Start Date: Reactivated 1992 (6) Est Compl Date:

(7) Principal Investigator: Daniel Tell, LTC, MC (8) Facility: FAMC

(9) Dept of MED, Hem/Onc Svc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV . b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: WRAMC closed this protocol approximately three months ago due to slow accrual. Two patients enrolled at FAMC, both patients progressed on treatment and have expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/115 (3) Status: Ongoing

(4) Title: The Impact of an Ambulatory Care Rotation on Interns
Psychosocial Attitudes

(5) Start Date: 1989 (6) Est Compl Date: 1998

(7) Principal Investigator: Michael J. Weaver, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. Svc. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 24
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: We propose to test the hypotheses that this ambulatory care rotation will result in increased awareness of psychosocial problems and the increase in awareness will be correlate with an increase in knowledge of psychosocial content.

(16) Technical Approach: Each intern who does a one month ambulatory care rotation in the internal medicine clinic is given a cognitive knowledge test and a psychosocial attitudes questionnaire at the beginning of the rotation, and again at the end of the rotation.

(17) Progress: Two years of questionnaires have been administered to interns who are now junior and senior residents. Protocol was amended in May 92 to extend the study up to 6 years, administering the same questionnaire to these residents to determine the long-term changes in attitude through training and into their first years of practice or subspecialty training.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/120 (3) Status: Completed

(4) Title: Ventilatory Effects of Transtracheal Oxygenation

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:
Michael Perry, COL, MC
Peter Blue, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Pulmonary Dis.

(10) Associate Investigators:
Douglas Dothager, CPT, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 15

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the ventilatory effects of transtracheal oxygen therapy.

(16) Technical Approach: A group of 10 COPD patients will have their resp. parameters measured while receiving supplemental oxygen through a nasal cannula and then again while receiving transtracheal oxygen at a flow rate equivalent to that of the nasal cannula. The 2nd part of the study will examine the effects of transtracheal oxygen on radioactive xenon wash.

(17) Progress: Computer program modified as per ammendment. One new patient enrolled since modification. Findings included a reduction in minute ventilation in excess of the displaced deadspace as a result of the distribution of ventilation peculiar to emphysema patients. Physiologic deadspace was found to match the reduction in minute ventilation as a result of methemathical redundancy.

Publications and Presentations: HMLAC, Oct 88, 89; Army ACP meeting; An. Thoracic Soc. May 89; Abstract: Review of Am. Respiratory, Apr 89. HMLAC 1991, An. Thoracic Soc. May 91, Abstract, Am Rev. Resp. Dis., April 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/121 (3) Status: Ongoing

(4) Title: Bone Densitometry in Thyroid Extract Treated Patients

(5) Start Date: 1988

(6) Est Compl Date: 1995

**(7) Principal Investigator:
William J. Georgitis, LTC, MC**

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine Svc

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period: 30 controls

d. Total Number of Subjects Enrolled to Date: 50

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether thyroid extract has greater adverse effects on bone density and calcium metabolism than synthetic l-thyroxine. The second is to assess the reversibility of any documented effect.

(16) Technical Approach: The effects of thyroid extract treatment on bone densitometry will be investigated. Subjects taking thyroid extract treatment matched with a thyroxine controlled group will have assessments of thyroid replacement therapy status, mineral metabolism and bone density. Thyroid extract subjects found to be subclinically hyperthyroid may enter a longitudinal assessment of bone density after crossing over to euthyroid thyroxine replacement.

(17) Progress: From eighty-five refill prescriptions for thyroid extract, seventy-one patients were sent letters. Twenty-eight potential subjects were counseled about the study and twenty have been studied. TRH tests, bone densities, and 24hr urine collections have been completed on 30 controls. Ten thyroid extract subjects have crossed over to thyroxine in the longitudinal phase of the study.

Publications and Presentations:

1. Georgitis WJ, Abrams LF, Dolbow A, Bunker DM: Bone densitometry in patients taking thyroid extract. Presented: American Society for Bone and Mineral Research/International Conference on Calcium-regulating Hormones. 1st Joint Meeting. Abstract 219:S172, Montreal, Quebec, September 1989.

2. Abrams L, Georgitis W, Dolbow A, Bunker D, Kidd G: Is anyone taking thyroid extract consistently euthyroid? The Endocrine Society, 72nd Meeting, Atlanta, GA, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/124 (3) Status: Ongoing

(4) Title: Corticosteroids in the Treatment of Stable Chronic Obstructive Pulmonary Disease

(5) Start Date: (6) Est Compl Date: 1992

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators: David L. Goodman, LTC, MC

(11) Key Words:
COPD
obstructive lung disease
corticosteroids

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 7 - complete 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine if subjects with severe obstruction lung disease would benefit from extended therapy with corticosteroids.

(16) Technical Approach: Approximately 10 subjects who have COPD that is not responsive to maximal beta-agonist therapy will be enrolled (elevated FEC, <10%) they will then be randomized to receive either 32mg methylprednisolone per day or placebo for 4 weeks followed by a washout period of 4 weeks and finally crossover to receive the alternate drug. Spirometry and body plethysmography will be performed prior to beginning the study and at 2 week intervals throughout the study period.

(18) Progress: Seven subjects enrolled; Seven complete. Patient recruitment is somewhat difficult in that most "irreversible" COPD subjects have demonstrated a >10% response to B2 therapy. B2 therapy still remains a problem. No fellow currently involved in study. Although patients with appropriate entry criteria remain very difficult to recruit, we will try to find 3 additional patients to complete the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/102 (3) Status: Ongoing

(4) Title: Factors Determining Peak Bone Mass and Subsequent Bone Loss

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Michael T. McDermott, LTC, MC
Gerald S. Kidd, COL, MC
Peter W. Blue, COL, MC
Harry N. Tyler, Jr., DAC

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrinology

(10) Associate Investigators:

(11) Key Words:
bone density
peak bone mass

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine factors associated with the development of peak bone mass and subsequent bone loss.

(16) Technical Approach: Bone density of the radius (single photon absorptiometry) and of the hip and spine (dual photon absorptiometry) will be done in a large group of male and female volunteers, who will also, on another protocol, be having total body fat and lean mass measured by dual photo absorptiometry. Questionnaire concerning present and past calcium intake, exercise and other habits will also be administered.

(17) Progress: No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 89/103 (3) Status: Ongoing
-
- (4) Title: Transient Hypoxia During Sedated Endoscopic Procedures
-
- (5) Start Date: Dec 88 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: Stephen Freeman, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Gastroent (10) Associate Investigators: Steve Lawrence, LTC, MC
Scott Hallgren, MAJ, MC
Jeffrey Dunkelberg, MAJ, MC
John Van Deren, CPT, MC
-
- (11) Key Words: endoscopy
hypoxia
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Nov b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the incidence of transient hypoxia during sedated endoscopy and correlate this with changes in blood pressure, cardiac rhythm, overall clinical status of the patient and type and/or stage of endoscopy.
-
- (16) Technical Approach: Room air arterial oxygen saturation, blood pressure and heart rate will be recorded prior to, during and after intravenous sedation and endoscopy.
-
- (17) Progress: No progress has been made on this protocol in FY90. The protocol, however, should remain active. Adequate monitoring equipment to simultaneously monitor oxygenation, blood pressure, heart rate, and ECG has heretofore been lacking. Equipment which will allow such monitoring has finally been purchased as of 30 Sep 91. It is anticipated by the principal investigator that the protocol can be finally carried out to completion during FY92.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/104 (3) Status: Ongoing

(4) Title: Efficacy of Corticosteroids in the Acute Treatment of
Asthma: Is Duration of Symptoms Important?

(5) Start Date: Sep 89 (6) Est Compl Date: Sep 91

(7) Principal Investigator: Thurman R. Vaughan, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy (10) Associate Investigators:
David L. Goodman, LTC, MC

(11) Key Words:
asthma
corticosteroids
emergency management

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if the beneficial effect of
corticosteroids seen in the treatment of status asthmatics is dependent
on the duration of asthmatic symptoms.

(16) Technical Approach: 120 subjects presenting to the E.R. or allergy
clinic with acute episode of asthma will be studied. Subjects will
receive either 125mg methylprednisolone or placebo within 30 minutes of
arriving for tx. They will be divided into 2 sps - these with IRS of
<24 hours duration and those with sx's for more than 24°. Spirometry and
admission rate will be analyzed.

(17) Progress: No current fellow assigned to protocol. Will assign a
new first year this fall.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/105 (3) Status: Ongoing

**(4) Title: Appropriate Blood Pressure Control in Diabetes Trial
Protocol (ABCD Trial)**

(5) Start Date: 1991 (6) Est Compl Date: 1998

(7) Principal Investigator: Gerald S. Kidd, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine (10) Associate Investigators:

**(11) Key Words:
nephropathy
diabetes**

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 32
d. Total Number of Subjects Enrolled to Date: 42
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" To day • no serious adverse events by FAMC patients thought to be secondary to study involvement.**

((15) Study Objective: a) Define a level of blood pressure control in a prospective, randomized, non-blinded fashion needed to prevent or delay the progression of diabetic nephropathy and other microvascular complications of diabetes; b) determine if there is a specific advantage to either a CEI or a Ca++ channel blocker as a mode of treatment for hypertension in regard to the onset or progression of diabetic nephropathy.

(16) Technical Approach: See protocol.

(17) Progress: Approximately 42 Fitzsimons Army Medical Center patients have been enrolled in the protocol without complications. Apparently city-wide approximately 700 patients have agreed to participate, and several hundred are actively involved.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/108 (3) Status: Ongoing

(4) Title: Efficacy of Pentoxifylline in Treating Diabetic Impotence

(5) Start Date: 1989

(6) Est Compl Date: 1992

(7) Principal Investigator:

(8) Facility: FAMC

John A. Merenich, MAJ, MC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:

(11) Key Words:
diabetes
impotence
pentoxifylline

Nancy Pfander, MAJ, MC
William Georgitis, LTC, MC
Gerald S. Kidd, COL, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 19 _____
d. Total Number of Subjects Enrolled to Date: 21 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if pentoxifylline is more effective than placebo in improving sexual function in non-insulin dependent diabetic men.

(16) Technical Approach: A single center, double-blind, placebo controlled study to examine the efficacy of pentoxifylline in improving sexual function in impotent NIDDM men. Diabetic men with impotence who meet the protocol entrance criteria will be randomly assigned placebo or pentoxifylline for 12 weeks. After completion of the treatment course subjects will be reevaluated, and groups will be compared to determine beneficial effects.

(17) Progress: Twenty-one subjects have completed the protocol. Twenty-four more subjects contacted; counseled, but have not started medication.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/109 (3) Status: Ongoing

(4) Title: The Effect of Percutaneous Endoscopic Gastrostomy
Tube Placement on Gastric Emptying

(5) Start Date: Jan 89 (6) Est Compl Date:

(7) Principal Investigator: Stephen Freeman, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Int. Med. (10) Associate Investigators:
Jeffery Dunkelberg, MAJ, MC

(11) Key Words: gastric emptying
gastrostomy tube Scott E. Hallgren, MAJ, MC
Peter Blue, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To define the effect of PEG placement on gastric
emptying.

(16) Technical Approach: Baseline gastric emptying studies will define
subjects' status prior to PEG placement. Repeat gastric emptying
studies at definite intervals post procedure will allow detection of any
changes in gastric emptying. This will impact possibly on defining a
standard approach to feeding these patients.

(17) Progress: The first five patients who met study criteria and were
completely evaluated were presented at the WBAMC GI symposium.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/111 (3) Status: Terminated

**(4) Title: Multicenter Clinical Evaluation of Penicillin
Skin Testing Materials**

(5) Start Date: 1989

(6) Est Compl Date:

**(7) Principal Investigator:
Richard Weber, COL, MC**

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc

**(10) Associate Investigators:
James Brown, COL, MC
Robert Ledoux, DAC**

**(11) Key Words:
penicillin**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

(14) a. Date, latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 21
d. Total Number of Subjects Enrolled to Date: 180
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the optimal test reagent in assessment for anaphylactic grade sensitivity to minor determinants of penicillin.

(16) Technial Approach: Prick and intradermal skin testing.

(17) Progress: 180 patients have been studied to date. Findings: Good positives for all minor determinant mixes used. Problems: No studies to determine sensitivity or specificity. Study terminated FY 92.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/115 (3) Status: Terminated

(4) Title: The Effect of Congestive Heart Failure (CHF) on the Erythrocyte Sedimentation Rate (ESR)

(5) Start Date: Aug 89 (6) Est Compl Date:

(7) Principal Investigator: Ben Mendoza, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Cardiology Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To establish the effect of acute uncomplicated CHF on the ESR and attempt to analyze specific variables affecting the ESR in the setting of CHF.

(16) Technical Approach: Fifty patients evaluated will be admitted for routine elective cardiac catheterization while fifty patients evaluated will be admitted for treatment of congestive heart failure. This study will analyze certain blood chemistries that are not routinely drawn for examination in patients with CHF or for routine cardiac catheterization.

(17) Progress: Control subjects have been entered into the study. Patient's with CHF have been difficult to obtain. Many were excluded because of acute MI, some with CHF could not have appropriate labs drawn. Protocol was administratively terminated FY 92.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/100 (3) Status: Ongoing

(4) Title: Platelet Thromboxane and Aggregation and Whole Blood Prostacyclin Synthesis in Human Thyroid Disease

(5) Start Date: 1990

(6) Est Compl Date: 1992

(7) Principal Investigator:
Jan Perloff, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrinology

(10) Associate Investigators:

(11) Key Words:

Gerald S. Kidd, COL, MC
John A. Merenich, MAJ, MC
Michael T. McDermott, LTC, MC
Chris White, MAJ, MS
Lynn Abrams, CPT, MC
Sharon Noble, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the roles of thromboxane and prostacyclin in mediating the phenomenon associated with thyroid dysfunction.

(16) Technical Approach: See protocol.

(17) Progress: As of this date pre- and post- data have been completed on 15 patients. About 15 more patients are required to complete the study. No complications. Laboratory methods are analysis are progressing well. New investigators have been added to the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/102 (3) Status: Ongoing

(4) Title: Effect of Prolonged Administration of Iodine Containing Water Purification Tablets in Man

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Michael T. McDermott, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrinology (10) Associate Investigators: William J. Georgitis, LTC, MC
Homer LeMar, MAJ, MC

(11) Key Words:
iodine
goiter
thyroid

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8
d. Total Number of Subjects Enrolled to Date: 8
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prolonged iodine administration (3 mos) causes persistent hypothyroidism or if compensation occurs and if goiters occur.

(16) Technical Approach: Iodine containing water purification tablets (4 tabs/day, 8mg iodine/tab) will be given to 15 subjects for 3 months. Baseline studies will include thyroid hormone and TSH levels, a TRH test, a radioactive iodine uptake and thyroid ultrasound thereafter, thyroid hormone levels, tSH and TRH test will be repeated at 7, 28 and 90 days. The radioactive iodine uptake will be separated at 7 and 90 days and the thyroid ultrasound will be repeated at 90 days.

(17) Progress: Six volunteers have completed the entire study and two more will complete it in the 2nd week of Aug 1992. Complete data analysis will not be done until all data is collected. However, preliminary analysis shows that after one week of taking iodine containing water purification tablets; T4 and T3 decreased, TSH increased and the radioactive iodine uptake (RAIU) was suppressed in all subjects. After 5 weeks these changes were more marked and the thyroid size increased in all subjects. After 13 weeks the changes persisted and thyroid sized was further increased.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/103 (3) Status: Ongoing

(4) Title: The Limulus Amoebocyte Lysate Assay for the Diagnosis
of Spontaneous Bacterial Peritonitis in Ascitic Fluid

(5) Start Date: 1990 (6) Est Compl Date: June 1991

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Gastro. (10) Associate Investigators:
Stephen Freeman, LTC, MC

(11) Key Words:
limulus
SBP

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 13
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e" None

(15) Study Objective: Determine efficacy of the limulus amoebocyte
lysate assay in the early diagnosis of Gram negative spontaneous
bacterial peritonitis.

(16) Technical Approach: The limulus assay is run on peritoneal fluid
obtained from patients with ascites, and then compared to standard cell
count/culture definitions of SBP.

(17) Progress: No cases of gram negative SBP have been seen since the
onset of this study at this hospital. The cases examined to date were
all negative by the limulus assay, as would be expected. However,
several cases resulted in a negative inhibition control, indicating
reaction inhibition does occur.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/105 (3) Status: Ongoing

(4) Title: Incidence and Prevalence of Hematuria in Patients on Long-Term Anticoagulation

(5) Start Date: 1990

(6) Est Compl Date: 1992

(7) Principal Investigator:
James A. Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc

(10) Associate Investigators:
Talley F. Culclasure, CPT

(11) Key Words:
hematuria
anticoagulation

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: DEC b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 180
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess incidence and prevalence of hematuria in anticoagulated population.

(16) Technical Approach: UA performed monthly on patients in coumadin clinic.

(17) Progress: Approximately 240 Coumadin patients were followed for one year, resulting in approximately 3000 patient-months. The Coumadin group enrollment is now closed. Follow-up continues on the 100 control subjects.

Publications and Presentations: Abstract presented at Army Regional ACP meeting, San Francisco, Oct 91. Abstract published in J Am Society Neph, vol 2, pg 305, 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/108 (3) **Status:** Ongoing

(4) **Title:** Comparison of Impedance Plethymography, Venogram and Doppler Ultrasound in Diagnosing Deep Venous Thrombosis

(5) **Start Date:** 1990 (6) **Est Compl Date:** 1992

(7) **Principal Investigator:** David Kristo, CPT, MC (8) **Facility:** FAMC

(9) **Dept/Svc:** Int. Med. (10) **Associate Investigators:** Marin Kollef, MAJ, MC
James Luethke, CPT, MC

(11) **Key Words:**

(12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** JAN b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** 15
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To compare IPG and doppler vs and with venogram at this facility.

(16) **Technical Approach:** A blinded comparison fo the three studies.

(17) **Progress:** 15 patients enrolled to date. No further enrollment planned at this time. Publication pending.

Publications: Abstract sent to American Thoracic Society October 1990.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/109 (3) Status: Ongoing

(4) Title: Altitude Effects on Oxygen Kinetics During Exercise
in Acclimatized Fit Troops

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
Michael E. Perry, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pulmonary Svc

(10) Associate Investigators:
James Meyers, CPT, MC

(11) Key Words:
altitude
exercise
oxygen kinetics

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 29
d. Total Number of Subjects Enrolled to Date: 29
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate effects of altitude on exercise performance and oxygen kinetics in altitude-acclimatized troops.

(16) Technical Approach: Troops stationed at altitude for a least 1 year will undergo formal exercise testing both at altitude and at sea level.

(17) Progress: 29 subjects have completed studies at 5800 ft elevation (Ft. Carson) and -300 ft elevation (Death Valley, CA). Data indicates profound effects on ventilation parameters and also on oxygen kinetics.

Publications: Meyer JI, Perry ME, Browning RJ, Brunson R, Annan WM, LaFraucios GT, Ferris CF: Effects of intermediate altitude on oxygen kinetics in acclimatized fit subjects. Am Rev Resp Dis 143:A174 (suppl), 1991.

Perry ME, Browning, Jackson R, Meyer JI: The effects of intermediate altitude of the Army physical fitness test. Military Medicine.

Presentations: Altitude effects on PT testing in acclimatized troops. Presented: Carl Tempel Symposium, San Francisco, CA October 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/110 (3) Status: Ongoing

(4) Title: Effects of Altered Calcium on Blood Pressure

(5) Start Date: 1990

(6) Est Compl Date: 1992

(7) Principal Investigator:
James A. Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology Svc

(10) Associate Investigators:
Philip S. Travis, MAJ, MC

(11) Key Words:
renal failure
dialysis
hypercalcemia

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Establish the effect of high calcium dialysate with calcium supplementation vs low calcium dialysate without calcium supplementation on blood pressure.

(16) Technical Approach: Randomized prospective crossover study utilizing a low or high calcium dialysate bath in the correction of hypertension in patients with renal failure.

(17) Progress: Patient enrollment continues. Insufficient data for analysis at this time. No progress on research due to Desert Storm commitments.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 90/112 (3) Status: Ongoing

(4) Title: Laboratory Screening to Detect Biochemical Evidence of Hemochromatosis Among Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM)

(5) Start Date: 1990

(6) Est Compl Date: 1992

**(7) Principal Investigator:
John A. Merenich, MAJ, MC**

(8) Facility: FAMC

(9) Dept/Svc: Endocrine

**(10) Associate Investigators:
Michael T. McDermott, LTC, MC
Donna Bunker, DAC
Vishnu V. Reddy, LTC, MC
Darci D. Ashley, DAC**

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: MARCH b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 160 _____
d. Total Number of Subjects Enrolled to Date: 560 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: To provide a systemic means for all NIDDM patients at FAMC to be screened and to make physicians aware of the need for this intervention.

(16) Technical Approach: See protocol.

(17) Progress: Study will be finished in approximately 6 months (Summer '92). Protocol progress delayed secondary to Principal Investigator's involvement in Desert Storm.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 90/113 (3) Status: Completed

(4) Title: Effect of Cold Remedies on Metabolic Control of Noninsulin
Dependent Diabetes Mellitus

(5) Start Date: 1990 (6) Est Compl Date: 12/91

(7) Principal Investigator: Homer Lemar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Endocrine (10) Associate Investigators:
W.J. Georgitis, LTC, MC
Darci U. Ashley

(11) Key Words:
diabetes mellitus
sucrose
alcohol
antitussive

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MARCH b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 6
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e" None

(15) Study Objective: Determine if sugar and alcohol free cough
formulas have clinically significantly fewer adverse metabolic effects
inpatients with diabetes mellitus compared to standard (sugar and
alcohol containing) cough formulas.

(16) Technical Approach: Prospective crossover study in which all
subjects will take both preparations in series and effects on blood
sugar and lipids will be compared. Two groups of patients will be
studied (well controlled and poorly controlled) in this manner.

(17) Progress: Twenty subjects have been enrolled and have completed
the study. This completes the study. Finalization of statistical
analysis and the manuscript are underway.

Publications: None. Presentations: 6/91 Uniformed Society of
Endocrinologists as a Poster at the Endocrine Society Meeting in
Washington, DC; 10/91 Endocrine Subsection of Present Concepts in
Internal Medicine Meeting in San Francisco, CA.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/114 (3) Status: Ongoing

(4) Title: Assessment of Patient Utilities for Health Outcomes:
Influence on Aspirin Prophylaxis to Prevent Myocardial
Infarction

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
Michael J. Weaver, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Gen. Int. Med.

(10) Associate Investigators:
William Reed, MAJ, MC
(Letterman AMC)

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 72
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e" None

(15) Study Objective: To determine what patients' utilities are for
various health outcome states: (1) MI; (2) mild CVA; (3) moderate -
severe CVA. Determine whether patient utilities influence decision to
take ASA to prevent MI.

(16) Technical Approach: Decision analysis tree constructed using
probabilities from published trials of ASA as prophylaxis against MI.
Determine patient utilities by standard reference gamble interview.

(17) Progress: 70 subjects interviewed, data analysis and decision
analysis are currently ongoing.

Publications and Presentations: One presentation.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/115 (3) Status: Completed

(4) Title: Relationship of Blood Flow in Hemodialysis Access to
Recirculation with Variable Blood Pump Flow

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology

(10) Associate Investigators:
CPT Bergstrom

(11) Key Words:
recirculation
access
dialysis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 16
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e" None

(15) Study Objective: Relationship between blood pump flow rate and
recirculation.

(16) Technical Approach: Measure recirculation at variable blood pump
speeds.

(17) Progress: Twelve patients enrolled, no data yet.

Publications: Hasbargen J, Bergstrom, R: Effects of Variable Blood Pump
Speed (QB) on Recirculation. J. Am. Soc. Nephrology, 1:360, 1990.

Presentations: 23rd Annual Meeting of Am. Soc. Nephrology, Washington,
DC, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/116 (3) Status: Terminated

(4) Title: Smoking Cessation Enhancement by Estimated Lung Age and Measured Expiratory Carbon Monoxide Levels

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: Vance Bray, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Int. Med. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 42
d. Total Number of Subjects Enrolled to Date: 42
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Evaluate the effect of patient education based upon calculated lung age and measured carbon monoxide exhalation on smoking cessation.

(16) Technical Approach: Initial spirometry, carbon monoxide measurement and questionnaires will be repeated at 6, 12 and 18 months in groups participating in the current smoking cessation classes and groups of smokers not participating in the classes to evaluate the long-term success rate of patient education.

(17) Progress: Protocol progress has been impaired by temporary duty associated with operation desert shield/storm. Principal investigator has returned. No changes have been made in the protocol. The 6 month assessment was missed due to deployment but will begin at the 12 month interval in May, 1991.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/117 (3) Status: Ongoing

(4) Title: The Effect of Prolonged Thyroxine Suppression Therapy on Thyroid Nodule Size, Cytology and Serum Thyroglobulin in Patients with Solitary Palpable Thyroid Lesions

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
John Merenich, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrine

(10) Associate Investigators:

(11) Key Words:

Homer J. Lemar, MAJ, MC
Gerald S. Kidd, COL, MC
Michael McDermott, COL, MC
William Georgitis, COL, MC
Mark Larson, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if suppressive doses of levothyroxine (documented by an 'ultrasensitive' TSH assay) reduces the size (by ultrasound) of newly discovered, biopsy "non-malignant" thyroid nodules; if response to suppression therapy differs between patients with truly uninodular lesions VS those in whom ultrasound examination uncovers the presence of multiple nodules; if any FNA cytologic changes occur after a course of suppression therapy and the utility of serum thyroglobulin as a biochemical marker of changes in nodular size or cytology.

(16) Technical Approach: See protocol.

(17) Progress: No data yet, placebo to arrive by 1 September 90 and then the project can be started. FY 91, no progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/121 (3) Status: Completed

(4) Title: Temporal Course of Altitude Acclimatization

(5) Start Date: 1990

(6) Est Compl Date: 1992

**(7) Principal Investigator:
Michael Perry, COL, MC**

(8) Facility: FAMC

(9) Dept/Svc: MED/Pul. Dis. Svc.

(10) Associate Investigators:

**(11) Key Words:
altitude effects
acclimatization**

**William Annan, COL, IN
Harry Dolton, Jr., LTC, FA
Gerald Kidd, COL, MC
John O'Connor, LTC, IN**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: To determine the time requirement for completion of altitude-acclimatization.

(16) Technical Approach: Subjects' anaerobic threshold will be determined using a 2-mile run and a two-part bicycle ergometer test at Ft. Sill. Arterial blood sample will be obtained. Using the same troops, the identical protocol will be carried out at Ft. Carson at 72 hrs, 1 mo, 6 mo, 9 mo, 12 mo, and 18 mo after arrival for duty with the 4th ID.

(17) Progress: Approximately 20 subjects at Ft. Sill have undergone testing according to protocol guidelines. The same subjects are now undergoing testing at Ft. Carson. Next testing period is May 91 then Nov 91.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/122 (3) Status: Ongoing

(4) Title: Evaluation of Viral Hepatitis in Patients Infected with the Human Immunodeficiency Virus (HIV)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Kenneth Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastro. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the prevalence of serologic markers of viral hepatitis including hepatitis B, hepatitis C, and hepatitis D in a military population and to determine the effect of AZT therapy on the markers of HB infection.

(16) Technical Approach: Bank sera of 220 HIV subjects will be used. Sera banked prior to AZT therapy will be studied using qualitative hepatitis B DNA probe assay. Data will be correlated to helper: suppressor status and serum markers of hepatic injury. Hepatitis C assay by ELISA will be performed on serial serum samples and at 6 months to 1 yr intervals to determine the incidence of hepatitis C in this population. Hepatitis D antibody testing will be performed in all HBsAG positive samples as well as any that may be HBV DNA positive but antigen negative on testing.

(17) Progress: Subset of patients with stored serum identified based on presence of serial blood samples; all serum tested for hepatitis C antibody by ELISA assay; positive samples confirmed with RIBA assay. A further subset of samples has been evaluated for hepatitis B genomic markers using Polymerase chain reaction technique.

Work is continuing on characterization of hepatitis viruses in stored HIV sample population. 50 samples have been tested for HCV viral RNA and HBV viral DNA by Polymerase Chain Reaction. Efforts are now underway to quantitate hepatitis C viral genome in HIV patients and compare this to hepatitis C in patients not HIV infected. A collaboration for comparing quantitative PCR methodologies with Chiron Corp. (Emeryville, CA) is being developed.

Publications:

Sherman KE, Freeman S, Harrison S, Andron L: Prevalence of Antibody to Hepatitis C Virus in Patients Infected with the Human Immunodeficiency Virus. J. Inf. Dis, 163:414-415, 1991.

Sherman KE, O'Brien J, Gutierrez A, Morse P, Freeman S, Andron L, Harrison, S. Serologic and Genomic Markers of Viral Hepatitis in Patients with HIV Infection. (Abstract) Gastroenterology, (in press).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/123 (3) Status: Terminated

(4) Title: Urinary Indices in Acute Renal Failure

(5) Start Date: 1990

(6) Est Compl Date: 1993

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephro.

(10) Associate Investigators:

(11) Key Words:
renal failure
serum creatinine

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate the use of several tests in diagnosing acute renal failure.

(16) Technical Approach: Prospective survey of serum creatinine in hospitalized patients for acute renal failure. Review of urinary diagnostic indices to include U/P creatinine, osmolality, FENA and FECL, FELI, NMR spectroscopy and transmission electron microscopy of urine as well as chart review.

(17) Progress: Terminated due to lack of funding

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/124 (3) Status: Completed

(4) Title: The Effectiveness of Octreotide (Sandostatin*) to Prevent Pancreatitis Caused by Endoscopic Pancreato-Biliary Procedures: A Double-Blind, Randomized Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Peter McNalley, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Gastroent. (10) Associate Investigators: Stephen Freeman, COL, MC
(11) Key Words: pancreatitis Scott Hallgren, MAJ, MC
octreotide Michael Fisher, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if administration of octreotide will decrease the risk of pancreatitis associated with endoscopic pancreato-biliary procedures and facilitate ampullary cannulation by decreasing S.O. and small bowel motility.

(16) Technical Approach: Patients undergoing endoscopic pancreato-biliary procedures will be randomized to either a treatment or placebo group, given 5-6 hours pre- and then immediately post procedure. After each procedure the investigators will perform an abdominal exam and interview directed toward the presence or absence of pain. Cholangiopancreatography will be done by standard method.

(17) Progress: Currently undergoing interim data analysis. The study is completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/125 (3) Status: Completed

(4) Title: SWOG 8697 Phase III Combination Chemotherapy of Predominantly Hormone Insensitive Metastatic Breast Cancer: An Evaluation of CAF Versus Rotating Regimens of CAF and TSAVBH Induction Therapy Followed by Observation or Maintenance Therapy with CMF(P)TH or CMFH---Intergroup

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment method.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/126 (3) Status: Ongoing

(4) Title: SWOG 8710 Trial of Cystectomy Alone Versus Neoadjuvant
M-VAC + Cystectomy in Patients with Locally Advanced
Bladder Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: One patient enrolled; doing well s/p radical
cystectomy.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/127 (3) Status: Completed

(4) Title: SWOG 8737 A Phase III Study, AZQ 24 Hour Infusion Versus BCNU for Adult High Grade Gliomas (Intergroup 0093)

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient's family refused chemotherapy; pt taken off study; Disease progress, pt has died.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/128 (3) Status: Completed

(4) Title: SWOG 8750 Pilot Study to Examine Cytogenic Abnormalities
in Patients with Acute Leukemia, Ancillary

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Study is closed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/129 (3) Status: Ongoing

(4) Title: SWOG 8814 A Phase III Comparison of Adjuvant Chemoendocrine Therapy with CAF and Concurrent or Delayed Tamoxifen to Tamoxifen Alone in Postmenopausal Patients with Involved Axillary Lymph Nodes and Positive Receptors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/130 (3) Status: Ongoing

(4) Title: SWOG 8899 A Prospective, Randomized Trial of Low-Dose Leucovorin + 5-FU, High-Dose Leucovorin + 5-FU, Levamisole +5-FU, or Low-Dose Leucovorin +5-FU + Levamisole Following Curative Resection in Selected Patients with Dukes' B or C Colon Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective treatment.

(17) Progress: One patient enrolled; patient completed chemotherapy; now in remission.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/131 (3) Status: Terminated

(4) Title: VA Cooperative Study No. 316: Efficacy of Passive Immunization in the Prevention of Infection Due to Klebsiella Penumoniae and Pseudomonas Aeruginosa

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
William Byrne, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc

(10) Associate Investigators:

(11) Key Words:
IVIG

Marion Kollef, MAJ, MC
Phillip Mallory, MAJ, MC
Thomas Cosgriff, COL, MC
Robert Gates, LTC, MC
Shannon Harrison, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if prophylactic administration of hyperimmune IVIG will prevent the acquisition of infection with those Klebsiella and P. aeruginosa serotypes included in the vaccine and that it will delay the onset and/or decrease the severity of infection in those patients who do become infected with these strains.

(16) Technical Approach: See protocol.

(17) Progress: Five patients enrolled, four survive, one expired due to cancer. The protocol is terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/132 (3) Status: Ongoing

(4) Title: Prevention and Treatment of Steroid Induced Osteoporosis

(5) Start Date: 1990

(6) Est Compl Date: 1994

**(7) Principal Investigator:
Michael McDermott, LTC, MC**

(8) Facility: FAMC

(9) Dept/Svc: MED/Endocrine

(10) Associate Investigators:

**(11) Key Words:
osteoporosis
steroids**

**John Merenich, MAJ, MC
William Georgitis, LTC, MC
James Singleton, MAJ, MC
Sterling West, LTC, MC
James Brown, COL, MC**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 15
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: Prevention and treatment of steroid induced osteoporosis.

(16) Technical Approach: Randomized controlled prospective single blind evaluation of the efficacy of a coherence therapy regimen in the prevention and treatment of steroid induced osteoporosis.

(17) Progress: Patients are being studied with more undergoing enrollment. Four patients have withdrawn for personal reasons.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/133 (3) Status: Ongoing

(4) Title: The Effect of Terfenadine on Urination

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Madhukar Punja, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Allergy Svc (10) Associate Investigators:
Harry Spaulding, COL, MC
Brant Thrasher, CPT, MC
Craig Donatucci, MAJ, MC

(11) Key Words:
antihistamine

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if Terfenadine alters the urinary flow in normal, healthy men or in men with prostatic hypertrophy.

(16) Technical Approach: This was a randomized double blind, placebo-controlled, cross-over design. Study subjects were randomized to receive either 60mg Terfenadine or identical appearing placebo BID for 1 week each, with a washout period of 1 week between the two treatment periods.

(17) Progress: Evaluation: Subjects were seen on days 0, 7, 14, and 21 and had the following evaluations: (a) Prick skin tests were done at the allergy clinic. (b) Urine flow measurements were obtained at the urology clinic with the Lifetech uroflometer 1-2 hrs before being seen at the allergy clinic. Peak and average urine flow rates were recorded at each visit.

RESULTS: Phase I: 8 normal, health volunteers <40 years age were evaluated. There was no alteration in urinary flow after 1 week of terfenadine. Phase II: 11 men with symptomatic, documented benign prostatic hypertrophy were enrolled from the Urology clinic. There ages ranged from 61-74 years. Mean skin test suppression was 85% after 1 week of Terfenadine and 4.14% after 1 week of placebo ($P < 0.001$). Mean value of the average urine flow rates of all patients was 9.7 cc/sec at baseline and 9.4 cc/sec after 1 week of Terfenadine ($P = 0.77$). Mean

value of the peak urine flow rates of the patients was 17.8 cc/sec at baseline and 18 cc/sec after 1 week of Terfenadine ($P=0.55$). None of the subjects complained of any urinary problems during the entire study period.

CONCLUSION: Recommend doses of terfenadine do not alter urinary flow in men with benign prostatic hypertrophy. We plan to use the same model in future, to evaluate other traditional antihistamines like chlorpheniramine maleate or diphenhydramine hydrochloride which have more potent anticholinergic properties.

Publications and Presentations: American Academy of Allergy & Immunology, San Francisco, Ca, Presented March 1991. Aspen Allergy Meeting, July 1991, Presented.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/134 (3) Status: Ongoing

(4) Title: Fibrinolytic and Thrombotic Activity in Unstable Coronary Disease

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
Mark Dorogy, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Cardiology

(10) Associate Investigators:
Christopher Kozlowski, CPT, MC
Thomas Cosgriff, COL, MC
bohdan Kudryk, Ph.D.

(11) Key Words:
fibrinopeptide anlaysis
coronary disease

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 28

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the relative contributions of thrombosis and fibrinolysis in the development of acute myocardial infarction and unstable angina.

(16) Technical Approach: Specific markers of thrombosis and fibrinolysis will be studied. These markers are the fibrinopeptide A, and two other fibrinopeptides known as B-beta-1-42 and B-beta-15-42.

(17) Progress: Twenty eight patients enrolled. Collection technique being refined after analysis of first 18 patients.

Publications and Presentations: Being presented at the Army ACP meeting October 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/135 (3) Status: Terminated

(4) Title: Comparison of Liver Biopsy Versus Noninvasive Testing Using Hepatic Ultrasound, Radionuclide Scanning, Erythrocyte Folate Levels and Methotrexate Levels for the Determination of Methotrexate-Induced Hepatotoxicity

(5) Start Date: 1990

(6) Est Compl Date: 1997

(7) Principal Investigator:
Stephen Freeman, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Gastro

(10) Associate Investigators:
Jeffrey Dunkelberg, MAJ, MC

(11) Key Words:
methotrexate
hepatotoxicity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To correlate the findings at the time of liver biopsy with blood tests as well as images of the liver obtained by ultrasound and nuclear imaging of the effect of methotrexate on the liver.

(16) Technical Approach: See protocol.

(17) Progress: Principal Investigator is retiring and no new PI is being assigned. Study should be terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/136 (3) Status: Completed

(4) Title: SWOG 8921 A Phase II Trial of Cyclophosphamide/IL-2,
DTIC/IL-2 and DTIC/Cisplatin/Tamoxifen in Stage IV
Melanoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Study is closed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/137 (3) Status: Completed

(4) Title: SWOG 8312 Megestrol Acetate and Aminoglutethimide/
Hydrocortisone in Sequence or in Combination as
Second-Line Endocrine Therapy of Estrogen Receptor
Positive Metastatic Breast Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est. Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Closed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/139 (3) Status: Completed

(4) Title: SWOG 8621 Chemo-Hormonal Therapy of Postmenopausal
Receptor-Positive Breast Cancer, Phase III

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est. Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Study is closed.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/140 (3) Status: Ongoing

(4) Title: SWOG 8692 Therapy in Premenopausal Women with Advanced
ER Positive or PgR Positive Breast Cancer: Surgical
Oophorectomy vs the LH-RH Analog, Zoladex. Phase III
Intergroup

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est. Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/141 (3) Status: Ongoing

(4) Title: SWOG 8711 A Study of Reproductive Function in Patients with Testicular Cancer

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/142 (3) Status: Ongoing

(4) Title: SWOG 8736 Treatment of Localized Non-Hodgkin's Lymphoma:
Comparison of Chemotherapy (CHOP) to Chemotherapy Plus
Radiation Therapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/143 (3) Status: Ongoing

(4) Title: SWOG 8793 Randomized Phase III Evaluation of Hormonal Therapy Vs Observation in Patients with Stage D1 Adenocarcinoma of the Prostate Following Pelvic Lymphadenectomy and Radical Prostatectomy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient enrollment.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/144 (3) Status: Ongoing

(4) Title: SWOG 8794 Treatment of Pathologic Stage C Carcinoma of the Prostate with Adjuvant Radiotherapy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient continues to do well one year after surgery.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/146 (3) **Status:** Ongoing

(4) **Title:** SWOG 8809 A Phase III Study of Alpha Interferon Consolidation Following Intensive Chemotherapy with ProMACE-MOPP (Day 1-8) in Patients with Low Grade Malignant Lymphomas

(5) **Start Date:** _____ (6) **Est Compl Date:** _____

(7) **Principal Investigator:** Thomas Cosgriff, COL, MC (8) **Facility:** FAMC

(9) **Dept/Svc:** MED/Hema/Oncol (10) **Associate Investigators:** _____

(11) **Key Words:** _____

(12) **Accumulative MEDCASE:*** _____ (13) **Est Accum OMA Cost:*** _____
*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** JAN b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** _____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To participate in SWOG.

(16) **Technical Approach:** To determine the most effective cancer treatment.

(17) **Progress:** Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/147 (3) Status: Ongoing

(4) Title: SWOG 8819 Central Lymphoma Repository Tissue Procurement Protocol

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/148 (3) Status: Completed

(4) Title: SWOG 8836 A Study of Chest Irradiation Plus Concurrent
Daily Low-Dose Cisplatin Followed by High Dose Con-
solidation for Locally Advanced Non-Small Cell Lung Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Two pts. off treatment and in remission. One pt.
relapsed after consolidation tx. and is receiving hospice care. On pt.
died after induction tx.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/150 (3) Status: Ongoing

(4) Title: SWOG 8905 Phase II/III Study of Fluorouracil (5-FU) and
Its Modulation in Advanced Colorectal Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 90/151 (3) Status: Ongoing
-
- (4) Title: Extrinsic Positive End-Expiratory Pressure (PEEP) Effects on Functional Residual Capacity in Normal Subjects and in Ventilated Patients Experiencing Air Trapping (AUTO-PEEP)
-
- (5) Start Date: 1990 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: Ronald Jackson, Ph.D., DAC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Pul.Dis.Svc. (10) Associate Investigators: Marin Kolef, MAJ, MC
Phillip Mallory, MAJ, MC
Robert Browning, BS, DAC
Douglas Dothager, CPT, MC
-
- (11) Key Words: lung volume
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine lung volume changes when air-pressure is added through a ventilator in patients with lung disease on ventilators.
-
- (16) Technical Approach: Ventilated subjects will be placed in an "iron lung" which will be used to measure lung volumes and changes in lung volumes. Computer hookup to subject will allow measurement of lung volume changes. Air pressure will be added to the ventilator a little at a time and any change in lung volumes will be measured. Blood pressure and heart rate will also be monitored.
-
- (17) Progress: An attempt was made to study normals with the use of a spirometer after modifications to the lung were made. However, inertia and resistance of the spirometer prevented accurate measurements and an excessive delay resulted while waiting for the remaining equipment. While awaiting delivery of this additional material, a computer program was written to sample pn.umotachometer data with the laboratory computer, which will allow the first phase to proceed. Currently, the new hardware is being wired together for the program modification to run on a microcomputer to allow use in the ICU where the second phase of the protocol will take place. Excessive delays in equipment deliveries have slowed progress on this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/152 (3) Status: Ongoing

(4) Title: Residual Renal Function in Dialysis Patients

(5) Start Date: 1990

(6) Est Compl Date: 1991

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology

(10) Associate Investigators:
Barbara Hasbargen, RN, BSN
E. Fortenbery, MAJ, MC

(11) Key Words:
dialysis
renal function

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 5
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principal objective of the study is to elucidate the relationship between modality of dialysis and residual renal function.

(16) Technical Approach: Fifteen patients who are on hemodialysis and 15 patients who are on CAPD and approximately 6 patients that will change from one modality to the other will be studied using blood samples and renal scans.

(17) Progress: Patients are currently being enrolled on this study which was approved in August 1990.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/153 (3) Status: Ongoing

(4) Title: Relationship of Calcium and Glucose Metabolism on Blood Pressure

(5) Start Date: 1990

(6) Est Compl Date: 1991

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Nephrology

(10) Associate Investigators:
John Merenich, MAJ, MC

(11) Key Words:
hypertension
calcium
glucose

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 3

d. Total Number of Subjects Enrolled to Date: 3

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To allow for a more rational approach to antihypertensive therapy.

(16) Technical Approach: Evaluate the subgroups of essential hypertensives with respect to calcium/PTH axis, vs glucose/insulin axis, vs Na/renin axis. Specifically to evaluate the relationships of Ca/PTH and the potential role of diminished insulin release and hyperglycemia in essential hypertensives.

(17) Progress: Patients are currently being enrolled in this study which was approved in August 1990. There have been problems with determination of intracellular ca# and patient enrollment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/154 (3) Status: Ongoing

(4) Title: SWOG 8326 Evaluation of Combination Chemotherapy Using
High Dose Ara-C in Adult Acute Leukemia and Chronic
Granulocytic Leukemia in Blastic Crisis, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/155 (3) Status: Ongoing

(4) Title: SWOG 8810 Six Courses of 5-Fluorouracil and Cis-Platinum with Correlation of Clinical and Cellular DNA Parameters in Patients with Advanced, Untreated and Unresectable Squamous Cell Carcinoma of the Head and Neck, Phase II Pilot Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/156 (3) Status: Ongoing

(4) Title: SWOG 8812 Treatment of Limited Small Cell Lung Cancer with Concurrent Chemotherapy, Radiotherapy, with or without GM-CSF and Subsequent Randomization to Maintenance Interferon or No Maintenance

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: One patient randomized to GM-CSF developed severe orthostatic hypotension and thrombocytopenia. GM-CSF stopped. Both patients in remission and doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/157 (3) Status: Ongoing

(4) Title: SWOG 8828 A Phase II Trial of Carboplatin (CBDCA) in
Relapsed or Refractory Acute Myeloid Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/158 (3) Status: Ongoing

(4) Title: SWOG 8851 A Phase III Comparison of Combination Chemotherapy (CAF) and Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary Node-Positive, Receptor-Positive Breast Cancer

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/159 (3) Status: Ongoing

(4) Title: SWOG 8892 A Study of Radiotherapy with or without
Concurrent Cisplatin in Patients with Nasopharyngeal
Cancer, Phase III

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/160 (3) Status: Ongoing

(4) Title: SWOG 8897 Phase III Comparison of Adjuvant Chemotherapy with or without Endocrine Therapy in High-Risk, Node Negative Breast Cancer Patients and a Natural History Follow-up Study in Low-Risk, Node Negative Patients

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/161 (3) Status: Ongoing

(4) Title: SWOG 8910 Evaluation of Low Dose Continuous 5-Fluorouracil (5-FU) and Weekly Cisplatin (CDDP) in Advanced Adenocarcinoma of the Stomach, Phase II Pilot

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/162 (3) Status: Ongoing

(4) Title: SWOG 8915 A Phase II Study of 6-Thioguanine Administered
as 120 Hour Continuous Infusion for Refractory or Recurrent
Small Cell Carcinoma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/163 (3) Status: Completed

(4) Title: SWOG 8916 Evaluation of Merbarone in Pancreatic
Adenocarcinoma, Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/164 (3) Status: Ongoing

(4) Title: SWOG 8952 Treatment of Advanced Hodgkin's Disease - A
Randomized Phase III Study Comparing ABVD vs MOPP/ABV
Hybrid

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/165 (3) Status: Ongoing

(4) Title: SWOG 8997 A Phase III Chemotherapy of Disseminated Advanced Stage Testicular Cancer with Cisplatin Plus Etoposide with Either Bleomycin or Ifosfamide

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/166A (3) Status: Completed

(4) Title: Evaluation of Allergenic Cross-Reactivity Amongst
Cockroach Species

(5) Start Date: 1990

(6) Est Compl Date: 1991

(7) Principal Investigator:
David Goodman, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Allergy

(10) Associate Investigators:

T. Ray Vaughan, MAJ, MC

Anthony Henry, LTC, MC

Robert Ledoux, BS, DAC

Richard W. Weber, COL, MC

Duane J. Harris, LCDR, MC, USN

(11) Key Words:
cross-reactivity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 9

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of clinical hypersensitivity to cockroach, common insects, and mites in an atopic disease population; to determine if there is significant cross-reactivity among the five common cockroach pests in North America; to determine cross-reactivity among cockroach, other common indoor insect pests and mite antigens.

(16) Technical Approach: Animal models will be used to develop antisera specific for cockroach and other insect species under investigation in this protocol. Prior to skin testing blood will be drawn for immunochemical analysis. Subjects will then be skin tested.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/168A (3) Status: Terminated

(4) Title: A Histologic and Immunopathologic Study of the Skin and Internal Organs of MRL+/-Mice

(5) Start Date: (6) Est Compl Date: 1991

(7) Principal Investigator: Kathleen David-Bajar, MAJ, MC (8) Facility: FAMC VA Hospital, Denver

(9) Dept/Svc: MED/Dermatology (10) Associate Investigators: Cheryl Teuton, CPT
Lele Lee, MD

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 14
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: We predict that the MRL-+/- mice will have pathologic findings similar to those reported in MRL/lpr mice, but will develop these findings in a more delayed manner. Further, we predict that the lpr gene is not a prerequisite for autoimmune disease in the MRL mouse.

(16) Technical Approach: This autopsy study will involve 10 animals in each age group studied, 4,16,32,40,48 and 60 weeks or approximately 60-100 animals. Blood will be obtained, and various internal organs removed for pathologic studies. We will compare our findings with those reported for MRL/lpr mice and with findings reported in humans with lupus.

(17) Progress: The MRL+/- mice tissues were obtained from the laboratory of Dr. Tom Santoro at the VA Hospital in Denver. Since last annual review, we have learned that the mice were infected with multiple pathogens. Because of this, we do not believe the data is useful and terminated the project.

Publications and Presentations: David KM, Davis DA, Santoro JT, Lee LA: Antibody deposition is not critical for the development of skin disease in the MRL -+/- mouse. J Invest Dermatol 96:533, 1991.
David KM, Davis DA, Santoro TJ, Lee LA: Antibody deposition is not critical for the development of skin disease in the MRL-+/- mouse. Presented: Annual meeting of the Society for Investigative Dermatology, Seattle, WA, 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/169 (3) Status: Terminated

**(4) Title: The Effect of Steroid Therapy on Recovery After
Tonsillectomy**

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Glen Yoshida, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Otolaryn. (10) Associate Investigators:

**(11) Key Words:
steroids
tonsillectomy
anti-inflammatory**

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
***Refer to Unit Summary Sheet of this Report**

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate the effectiveness of steroids to reduce the incidence and severity of postoperative symptoms and complications in patients undergoing tonsillectomy.

(16) Technical Approach: Twenty adult subjects will be randomized to receive either steroid or placebo intravenously at the time of surgery. A total of three doses will be given every 6 hrs. Patients will be asked to answer questions pertaining to their postoperative course at 24 hrs, 2 weeks and 2 months.

(17) Progress: Study published showing the beneficial effects of post-op antibiotics in decreasing pain and complications after tonsillectomy.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/171 (3) Status: Completed

(4) Title: SWOG 8789 A Randomized Study of Etoposide plus Cisplatin and Etoposide Plus Carboplatin (CBDCA) in the Management of Good Risk Patients with Advanced Germ Cell Tumors

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: To determine the most effective approach for cancer patients.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/172 (3) Status: Ongoing

(4) Title: SWOG 8792 A Phase III Study of Alfa-n1 (Wellferon) as
Adjuvant Treatment for Resectable Renal Cell Carcinoma

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/173 (3) Status: Ongoing

(4) Title: SWOG 8842 Dihydroxyazacytidine in Malignant
Mesothelioma, Phase II

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Patient progressed on treatment. Patient has died. Open
for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/174 (3) Status: Completed

(4) Title: SWOG 8900 A Phase II Pilot of VAD and VAD/Verapamil for Refractory Multiple Myeloma

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/175 (3) Status: Ongoing
(4) Title: SWOG 8931 Phase III Comparison of Cyclophosphamide,
Doxorubicin and 5-Fluorouracil (CAF) and a 16-Week
Multi-drug Regimen as Adjuvant Therapy for Patients
with Hormone Receptor Negative, Node-Positive Breast Cancer

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: One patient enrolled, on chemotherapy, doing well.
Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/176 (3) Status: Ongoing

(4) Title: SWOG 8994 Evaluation of Quality of Life in Patients with
Stage C Adenocarcinoma of the Prostate Enrolled on
SWOG 8794

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: MED/Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open for patient accrual.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 90/177 (3) Status: Ongoing
-
- (4) Title: National Co-operative rHu Erythropoietin Study in Patients
with Chronic Renal Failure: A Phase IV Multi-center Study
-
- (5) Start Date: 1990 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: MED/Nephrology (10) Associate Investigators:
-
- (11) Key Words:
renal failure
erythropoietin
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 10
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Expand the safety profile of erythropoietin in
anemic patients with chronic failure. To understand the medical and
social impact of erythropoietin therapy on the United States chronic
renal failure population, including patients currently receiving
erythropoietin and patients receiving therapy for the first time.
-
- (16) Technical Approach: Active study of patients currently receiving
or starting on erythropoietin.
-
- (17) Progress: Data not yet analyzed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/179 (3) Status: Terminated

(4) Title: A Randomized Prospective Study of Pyrimethamine Therapy for Prevention of Toxoplasmic Encephalitis in HIV-Infected Individuals with Serologic Evidence of Latent Toxoplasma gondii Infection (CPCRA 001).

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Robert Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: MED/Inf.Dis.Svc. (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE, b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate clindamycin and pyrimethamine as prophylactic agents against toxoplasmic encephalitis in individuals who are coinfectd with HIV and latent t. gondii.

(16) Technical Approach: Multicenter, prospective, 2-arm, placebo-controlled pyrimethamine, placebo for pyrimethamine) randomized, modified double-blind study.

(17) Progress: Pyrimethamine was not effective and might even increase the death rate. It was obvious that there were fewer cases of toxoplasmic encephalitis than expected so this study would not achieve significance.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/100 (3) Status: Ongoing

(4) Title: SWOG 8515 - Evaluation of Menogaril (NSC-269148) in
Non-Hodgkin's Lymphoma, Phase II.

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Thomas Cosgriff, COL, MC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/101 (3) Status: Completed

(4) Title: SWOG 8721 - A Phase II Trial of Trimetrexate in the Treatment of Esophageal Cancer.

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/102 (3) Status: Ongoing

(4) Title: SWOG 8894 - A Comparison of Bilateral Orchiectomy with
or without Flutamide for the Treatment of Patients with
Histologically Confirmed State D₂ Prostate Cancer

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/103 (3) Status: Ongoing

(4) Title: SWOG 8906 - Evaluation of Merbarone in Hepatoma,
Phase II

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: No patient enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/104 (3) Status: Ongoing

(4) Title: SWOG 8925 - Evaluation of Cisplatin + VP-16 Followed by Mitotane at Progression if No Prior Mitotane OR Cisplatin + VP-16 Only if Prior Treatment with Mitotane in Advanced and Metastatic Adrenal Cortical Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/106 (3) Status: Ongoing

(4) Title: A Randomized, Controlled Trial of Interferon Alpha and Thymosin Alpha-1 in Patients with Hepatitis C Antibody Positive Chronic Active Hepatitis

(5) Start Date: 1991

(6) Est Compl Date: 1994

(7) Principal Investigator:
Kenneth Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Stephen Freeman, COL, MC
Zachary Goodman, MD, PhD
Kamal Ishak, MD, PhD

(11) Key Words:
hepatitis
interferon alpha
thymosin alpha-1
IND

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Demonstrate efficacy of recombinant interferon alpha 2b among military personnel and those eligible for care under the auspices of DOD for treatment of chronic hepatitis C. Attempt to augment the response to interferon using Thymosin alpha-1 as in a immunomodulator.

(16) Technical Approach: Randomized, three-arm study: 1) treatment with interferon alpha + placebo; 2) interferon alpha + thymosin alpha-1; and 3) placebo (controls). Six-month study cycles with 40 adult chronic hepatitis C patients per arm.

(17) Progress: The start of this investigation new drug protocol was delayed 10 months after IRC approval by HSC approval (Feb 91) and FDA approval (Aug (1). The first patient was enrolled in Aug 91. To date three patients have been enrolled and four more should start within the next several weeks. Recruitment efforts have been made in DOD Region III Medical Treatment facilities and future contact with other potential referral sites is planned.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/107 (3) Status: Ongoing
-
- (4) Title: Does Omeprazole (Losec*) Improve Respiratory Function in Asthma Patients with Gastroesophageal Reflux? A Double-Blind, Crossover Study
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Gastroenterology (10) Associate Investigators:
Harry Spaulding, COL, MC
Madhukar Punja, MAJ, MC
Michael Perry, COL, MC
Nancy Stocker, Phar. D.
Michael Fisher, MAJ, MC
Stephen Freeman, COL, MC
-
- (11) Key Words:
GI reflux
omeprazole
asthma
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Nov b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 20
d. Total Number of Subjects Enrolled to Date: 20 (10 randomized) _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: The purpose of this study is to determine whether asthmatic patients with GER will experience improved respiratory function when GER is treated with omeprazole.
-
- (16) Technical Approach: Patients will be randomized to drug or placebo and evaluated by a number of tests to include gastrointestinal investigation to evaluate for GER, intermittent pulmonary function testing, blood tests, esophageal manometry, Bernstein test, 24-hr. esophageal pH monitoring and EGD.
-
- (17) Progress: Adequate. Ten patients randomized of the 20 enrolled. Two had moderate asthma exacerbations (not hospitalized). One patient died in the placebo group, but this did not appear related to therapy.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/108 (3) Status: Terminated

(4) Title: A Comparison of the Efficacy of Superpotent Topical Steroids Versus Intralesional Steroids in the Treatment of Discoid Lupus Erythematosus

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dermatology

(10) Associate Investigators:

(11) Key Words:
discoid lupus erythematosus
superpotent topical steroids
intralesional steroids

Kathleen David, MAJ, MC
James Fitzpatrick, LTC, MC
Pamela Homas, CPT, MC
Brenda Kodama, CPT, MC
Charlotte Kutsch, MD

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of the study is to compare the efficacy of ultra-potent topical steroids versus intradermal injection of steroids in the treatment of DLE lesions.

(16) Technical Approach: Evaluators will be blinded. Patients will be randomized to either entire body group (which will be randomized to either topical or intradermal treatment) or half- and half- treatment group (which will be randomized to right-side or left-side body treatment injections).

(17) Progress: No progress. Although the protocol was approved by the FAMC IRC in Nov 90, the drug sponsor, GLAXO, is withholding the drug until approved by the FDA. Administratively terminated FY 92.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/109 (3) Status: Ongoing

(4) Title: SWOG 9037 - Prediction of Recurrence and Survival in Node-Negative Breast Cancer Patients Using a Panel of Prognostic Factors. A companion protocol to 8897

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 91/110 (3) **Status:** Ongoing

(4) **Title:** SWOG 8795 - Randomized Prospective Comparison of Bacillus Calmette-Guerrin and Mitomycin-C Therapy and Prophylaxis in Superficial Transitional Cell Carcinoma of the Bladder, with DNA Flow Cytometric Analysis, Phase III

(5) **Start Date:** 1991 (6) **Est Compl Date:**

(7) **Principal Investigator:** Thomas Cosgriff, COL, MC (8) **Facility:** FAMC

(9) **Dept/Svc:** Hema/Oncol (10) **Associate Investigators:**

(11) **Key Words:**

(12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** _____ b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** _____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To participate in SWOG.

(16) **Technical Approach:** To determine the most effective cancer treatment.

(17) **Progress:** No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/111 (3) Status: Completed

(4) Title: SWOG 8834 - A Phase II Evaluation of Fazarabine in
Central Nervous System Tumors

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Study is closed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/112 (3) Status: Ongoing

(4) Title: SWOG 8957 - Feasibility Trial of Post-Operative Radio-therapy + Cisplatin Followed by Three Courses of 5-FU + Cisplatin in Patients with Resected Head and Neck Cancer

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/113 (3) Status: Ongoing

(4) Title: The Effect of Recombinant Growth Hormone on Pulmonary Function in Patients with Chronic Obstructive Pulmonary Disease

(5) Start Date: 1991

(6) Est Compl Date: 1994

(7) Principal Investigator:
Homer LeMar, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Endocrinology

(10) Associate Investigators:

(11) Key Words:
growth hormone
COPD
investigational new drug

Michael McDermott, LTC, MC
Michael McCormack, CPT, MC
Marin Kollef, MAJ, MC
William Georgitis, LTC, MC
John Merenich, MAJ, MC
Michael Perry, COL, MC
Edwin Fortenbery, MAJ, MC
Nancy Pfander, MAJ, AN
Donna Dolan, CPT, RD

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 9

d. Total Number of Subjects Enrolled to Date: 13

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" No adverse reactions

(15) Study Objective: To test the effect of recombinant growth hormone on breathing ability.

(16) Technical Approach: Randomized, prospective, double-blind, placebo-controlled design using recombinant human growth hormone or sterile saline placebo in patients with severe chronic obstructive pulmonary disease currently under follow-up in the Pulmonary Clinic at FAMC. Patients will be treated for one year. Pre- and post course measurements such as hand grip strength, pulmonary function, tests of endurance, bone density, lean body mass and laboratory tests, will be taken and compared.

(17) Progress: Thirteen patients recruited and six have now started treatment (growth hormone or placebo). Recruitment continues. Two more will start treatment in December.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/114 (3) Status: Ongoing

(4) Title: Detection of Renal Artery Stenosis by Noninvasive Testing

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology

(10) Associate Investigators:

James Luethke, MAJ, MC

(11) Key Words:
renal artery stenosis
captopril
enalaprilat
renogram

Edwin Fortenbery, MAJ, MC

Allan Chantelois, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 10

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the specificity and sensitivity of Captopril challenge, Captopril renogram, Enalaprilat renogram, and duplex ultrasonography in the diagnosis of RAS compared to the standard arteriography.

(16) Technical Approach: All patients studies will undergo captopril challenge, captopril renogram, enalaprilat renogram, duplex ultrasonography and renal arteriogram. Power analysis will be conducted to determine requirements for total number of patients after first 20 enrolled.

(17) Progress: No progress this FY. Patient enrollment slower than anticipated. Data collection only to this point.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/115 (3) Status: Ongoing

(4) Title: Prediction of Maximum Exercise Ventilation by
Identification of Optimal Reciprocal Spirometric
Timed Volumes

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: J. Turner, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Disease (10) Associate Investigators:
Robert Browning, BS, DAC
(11) Key Words: Michael Perry, COL, MC
lung volume George Giacoppe, CPT, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 25
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To improve the prediction of maximum exercise
ventilation during incremental exercise testing.

(16) Technical Approach: Twenty normal and forty COPD subjects will
perform maximal inspiratory and expiratory vital capacity maneuver on a
standard water-seal spirometer while a computer collects volume-time
data. Computer iteration will yield theoretical optimal reciprocal
spirometric times volumes. Patients will then perform standard
incremental exercise studies, and the ventilation parameters observed at
maximum exercise will be compared with the spirometrically derived
predictions.

(17) Progress: Spirometry and exercise study data has been collected
from 25 subjects; 9 normals and 16 abnormals (people with flow data
consistent with OAD). The raw data from these studies is currently
under review, with the study continuing.

Publications and Presentations:

Poster Presentation: ALA/ATS 1991 International Conference, Anaheim, Ca,
May 1991.

Turner J, Perry ME, Browning RJ: Publication: ARRS:1432, no 4, April
1991 (A169).

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/116 (3) Status: Completed

(4) Title: SWOG 9038 - Extended Administration of Oral Etoposide and Cyclophosphamide for the Treatment of Advanced Non-Small Cell Lung Cancer

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Patient taken off study for progression of disease after one cycle, patient has died.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/118 (3) Status: Ongoing

(4) Title: SWOG 9013 - A Prospective Randomized Comparison of Combined Modality Therapy for Squamous Carcinoma of the Esophagus: Chemotherapy Plus Surgery versus Surgery Alone for Patients with Local Regional Disease, Phase III

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/119 (3) Status: Ongoing

(4) Title: SWOG 9039 - Evaluation of Quality of Life in Patients
with Stage D-2 Cancer of the Prostate Enrolled in
SWOG 8894

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/120 (3) Status: Ongoing

(4) Title: What is the Prevalence of Gastroesophageal Reflux in Patients with Sleep Apnea - A Prospective Evaluation

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
Robert Sudduth, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:

Michael Perry, COL, MC

(11) Key Words:
gastroesophageal reflux
sleep apnea

David Everett, E-6, RPSGT-CPFT
Shannon Harrison, LTC, MC
Peter McNally, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Dec b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine the prevalence of GER in adults with the sleep apnea syndrome.

(16) Technical Approach: Polysomnography will be performed in the usual fashion with monitoring of the following variables: EEG, electrooculogram, nasal air-flow monitor, oxygen saturation and respiratory effort. Probe will be placed to monitor esophageal pH and intra-esophageal pressure. Esophageal pH data will be graphically analyzed and compared to polysomnographic events, specially examining for correlation between acid reflux and episodes of apnea.

(17) Progress: No progress this FY. Protocol is ongoing, though there was a major delay due to equipment problems which are to be shortly resolved.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/121A (3) Status: Completed

(4) Title: The Effect of Low-Dose Methotrexate on Calcium, Vitamin D and bone Metabolism in Female Sprague-Dawley Rats.

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Kimberly May, CPT, MC, USAF (8) Facility: FAMC

(9) Dept/Svc: Rheumatology (10) Associate Investigators: Daniel Battafarano, MAJ, MC Sterling West, LTC, MC Michael McDermott, LTC, MC Edward Fortenbery, MAJ, MC

(11) Key Words: methotrexate bone metabolism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:* *Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results: c. Number of Subjects Enrolled During Reporting Period: d. Total Number of Subjects Enrolled to Date: 63 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objectives of the study are to determine the effect of low dose methotrexate administration on calcium and vitamin D metabolism, and bone mineral content in rats.

(16) Technical Approach: Per protocol approved by LACUC on 15 Jan 91.

(17) Progress: Other serum parameters to assess bone metabolism reveal significant decreased alkaline phosphatase in the MTX treated rats. Only problem was discussed previously; an episode of heat stress in which 3 experimental animals died. 12 additional rats will undergo the protocol study design.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/122 (3) Status: Ongoing

(4) Title: A Multicenter, Double-Blind Study to Evaluate the Safety and Therapeutic Efficacy of Omeprazole 20mg A.M. or 10mg A.M. as Compared to Placebo During 12/24 Months Maintenance Treatment of Patients with Duodenal Ulcer Healing Following 4 Weeks of Omeprazole 20mg A.M.

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:

(11) Key Words:
omeprazole
duodenal ulcer
investigational new drug

John Meier, MAJ, MC
Robert Sudduth, MAJ, MC
Nancy Stocker, Pharm.D.
Stephen Freeman, COL, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 12

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this investigational new drug study is to determine if patients identified to have a duodenal ulcer that is healed with omeprazole can be prevented from experiencing an ulcer relapse when given one of two dosages or concentrations of this medicine when compared to a placebo.

(16) Technical Approach: After endoscopy verifies ulcer healing with omeprazole, patients will be randomized to receive either maintenance treatment with omeprazole (10 mg or 20 mg each morning) or placebo. Laboratory tests and EGD will be performed.

(17) Progress: Twelve patients have been enrolled to date. The protocol has been formally modified to lengthen the duration of the maintenance period from 1 to 2 years for all patients who are willing and give informed consent. Enrollment (nation-wide) in the acute phase was completed 30 Nov 91. No additional patients will be enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/123 (3) Status: Ongoing

(4) Title: Relative Efficacy of Three Oxygen Delivery Systems in the Nocturnal Home Setting

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Scott Sample, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Pulmonary Disease (10) Associate Investigators: Michael Perry, COL, MC

(11) Key Words: hypoxemic lung disease

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which of three standard modes of oxygen delivery are the most efficacious in an ambulatory setting using nocturnal pulse oximetry as a measure of efficacy.

(16) Technical Approach: To compare the efficacy of transtracheal oxygen therapy, nasal cannula and reservoir pendant oxygen systems in an ambulatory setting using nocturnal pulse oximetry recorders in patients on home oxygen therapy.

(17) Progress: Nine patients have completed the study. One or two patients are followed on a weekly basis. Total of 15 subjects will be enrolled. Study needs to be extended due to non-availability of monitors and problems recruiting subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/124 (3) Status: Ongoing
-
- (4) Title: A Controlled, Randomized, Open Pilot Study to Investigate the Effects of Intra-arterial (or Intravenous) Atrial Natriuretic Peptide in the Treatment of Acute Renal Failure
-
- (5) Start Date: 1991 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Nephrology (10) Associate Investigators: James Luethke, MAJ, MC
-
- (11) Key Words:
investigational new drug
Gallopamil
atrial natriuretic peptide
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____ 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: This study should serve as a preliminary investigation as to whether two medications can reverse kidney failure and whether giving the medications directly into the arteries to the kidneys will be practical.
-
- (16) Technical Approach: Prospective study of effectiveness of atrial natriuretic factor versus Gallopamil in the treatment of acute renal failure. The medications will be given via the renal artery. Study recently amended for intravenous use.
-
- (17) Progress: Gallopamil discontinued secondary to principal investigator's request. Also protocol was amended to use the intravenous formulation, and in fact 3/4 subjects used the IV form. No additional patients enrolled.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/125 (3) Status: Ongoing

(4) Title: An Ultrastructural Study of the Dermal-Epidermal Junction Following Skin Splitting with Various Methods

(5) Start Date: 1991 (6) Est Compl Date: 1991

(7) Principal Investigator: Kathleen David-Bahar, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators:

Scott Bennion, LTC, MC

(11) Key Words: skin splitting Rodney Williams, SPC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: NA
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate a reproducible site of separation, routine use of such "split skin" methods that will become the standard for the indirect immunofluorescence evaluation of bullous skin disorders.

(16) Technical Approach: Specimens of discarded human adult skin and neonatal foreskin will be subjected to dermal-epidermal separation using each of three methods: NaCl, EDTA, and dispase. Each specimen will then be processed for electron microscopy, after incubation in specific monoclonal antibodies to known anatomic components of the dermal-epidermal junction. Two investigators independently evaluate and be blinded to the source of the specimens in making their assessments.

(17) Progress: Successful splitting of the skin has been accomplished with both the NaCl and the EDTA methods. This splitting has been evaluated with routine hematoxylin and eosin staining on the light microscopy level, demonstrating the split is occurring in the area of the basement membrane zone. We have had numerous difficulties in the methodology of our immunogold technique for mapping the split with monoclonal antibodies. Extensive technical trials and alterations have been tried. We have not yet had success in immunogold staining with our monoclonal antibodies to the basement membrane zone components, however, we have demonstrated staining using immunofluorescence techniques.

CONTINUATION SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol No. 91/125

With anti-laminin antibodies, the staining has appeared on the epidermal side of the split skin, and with anti-BG-3 antibodies, we have shown consistent staining on the dermal side of the split. Thus, we believe that the relevant antigens are preserved in our splitting techniques, and that technical problems are the likely reason for our lack of staining with immunogold techniques. We are pursuing the technical difficulties at this time.

FY 92 - No progress, just returned from two months maternity and annual leave.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/126 (3) Status: Ongoing

(4) Title: Efficacy of Oral Cromolyn Sodium in Documented Adverse Food Reactions, A Double-Blind Placebo-Controlled Trial with Food Challenges

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
Evan Matheson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:

Anthony Henry, LTC, MC
T. Ray Vaughan, MAJ, MC
Bryan Martin, MAJ, MC

(11) Key Words:
food reactions
cromolyn sodium

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the efficacy of oral cromolyn sodium in patients with documented adverse food reactions.

(16) Technical Approach: Food skin testing and breathing tests will be done followed by food challenges, using placebo or real food, to document subject's reaction. Subjects will be randomized to placebo or drug. After 10 days the subjects will be re-challenged in a double-blind fashion. After a two-week washout, subjects will be crossed over and the challenges repeated after 10 days.

(17) Progress: Seven patients screened, 3 entered protocol, 2 completed protocol, no adverse reactions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/127 (3) Status: Ongoing

(4) Title: Effectiveness of Simethicone to Improve Visibility During Colonoscopy When Given with a Peroral FLEET Diphosphate Laxative: A Double-Blind Randomized Placebo Controlled Study

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
Robert Sudduth, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Gastroenterology

(10) Associate Investigators:
Nancy Stocker-Stolpman, PharmD
Peter McNally, MAJ, MC

(11) Key Words:
colonoscopy

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Feb b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 10

d. Total Number of Subjects Enrolled to Date: 50

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine if the co-administration of simethicone with Fleet per oral bowel pre can improve preparation for colonoscopy.

(16) Technical Approach: The subject population (220) will be randomized to Fleet with simethicone or to Fleet with placebo. During colonoscopy the investigators will use a scoring system to evaluate the number of bubbles and visibility while examining five areas of the colon.

(17) Progress: Going fairly well with 40 patients studied - may need until Spring 92 to complete. Ten more enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/128 (3) Status: Terminated

(4) Title: A Prospective, Randomized, Open-Label Comparative Trial of Dideoxyinosine (ddI) versus Dideoxycytidine (ddC) in HIV-Infected Patients Who Are Intolerant of or Who Have Failed Zidovudine (ZDV) Therapy

(5) Start Date: 1991

(6) Est Compl Date: 1994

(7) Principal Investigator:
Robert H. Gates, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Infectious Disease

(10) Associate Investigators:
W. Russell Byrne, LTC, MC
P. Bakker, MSN
R. Wright, MAJ, MC
S.M. Harrison, LTC, MC

(11) Key Words:
HIV
ddI/ddC
investigational new drugs

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Mar b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To evaluate and compare the efficacy and toxicity associated with ddI and ddC in patients with HIV infection who are intolerant of or have failed Zidovudine therapy.

(16) Technical Approach: A 2-year, prospective, 2-arm, randomized, multicenter, comparative study. Switchover is optional once a primary endpoint has been met after 12 wk on the original drug assignment. Switchover may occur at any time once a drug intolerance endpoint has been met.

(17) Progress: This study was reported as completed in the FY 91 Annual Progress Report due to impending release of the drugs by the FDA. The NIH decided to continue the study. Six patients were enrolled in this study, two died during the study (not unexpectedly) and the remaining four have had no unexpected adverse experiences.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/129 (3) Status: Ongoing
(4) Title: SWOG 9046 - Evaluation of 10-EdAM in Patients with Squamous Cell Carcinoma of the Head and Neck, Phase II

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 91/130 (3) Status: Terminated

(4) Title: MGI 136-07-P90-03: A Double-blind, Randomized, Placebo Controlled Study of Diethyldithiocarbamate (DDTC) Used as a Protective Agent Against Cisplatin-Induced Toxicities in Patients with Small Cell or Non-Small Cell Carcinoma

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

DDTC
cisplatin-induced toxicities
lung cancer
investigational new drug

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Mar b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to determine whether DDTC significantly reduces cisplatin-induced side effects in patients treated with cisplatin for small cell or non-small cell lung cancer.

(16) Technical Approach: Multi-center, investigational new drug protocol sponsored by Molecular Genetics, Incorporated. By double-blind randomization patients will be treated with either cisplatin and VP-16 plus DDTC or Cisplatin and VP-16 plus a placebo. It is estimated that approximately five eligible subjects will be enrolled at FAMC treatment.

(17) Progress: Study is Terminated - No patients have been enrolled at FAMC, although there have been some patients worked up who were ineligible. As of 10 Feb 92 MCI has suspended enrollment and treatment while they assess available data on observed increase in the number of premature withdrawals from treatment in the DDTC treated group.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/131 (3) Status: Completed

(4) Title: Survey of Aerobic Bacteria in Chenopod and Amaranth Pollens
and Their Effects on Pollen Extracts Used for
Desensitization in Allergic Disease

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Lawrence Larson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:
Terese Copeland, MAJ, MC
T. Ray Vaughan, MAJ, MC
Leo Andron, LTC, MS
Pari Morse, DAC

(11) Key Words:
pollen extracts
aerobic bacteria

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Apr b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the following parameters: 1) Extent
of aerobic bacteria present in Chenopod-Amaranth pollen with
determination of different species and relative amounts. 2) The effects
of aerobic bacteria on the amounts and kinds of protein obtained during
the extraction of pollen will be assessed.

(16) Technical Approach: A number of highly technical laboratory
procedures will be performed according to the plan of the protocol.

(17) Progress: Laboratory procedures completed on bacterial survey.
Preliminary data has been submitted for presentation and publication.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/132 (3) Status: Ongoing

(4) Title: Amlodipine Cardiovascular Community Trial

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Nephrology

(10) Associate Investigators:

(11) Key Words:
hypertension
Amlodipine
investigational new drug

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the effectiveness of Amlodipine in the treatment of essential hypertension (diastolic blood pressure 95-110 off medications).

(16) Technical Approach: The study will include a 2-3 week placebo run-in phase followed by a 4-week efficacy phase and a 12-week maintenance phase. At that time, the study may be terminated or the patient may be extended on long-term followup dependent upon the patient's desires.

(17) Progress: Three patient enrolled in the study.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/133 (3) Status: Ongoing

(4) Title: SWOG 9111 - (EST 1690) Post-Operative Adjuvant Interferon Alpha 2 in Resected High-Risk Primary and Regionally Metastatic Melanoma, Intergroup

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in SWOG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/134 (3) Status: Ongoing

(4) Title: The Use of Cultured Skin Cells and Monoclonal Antibodies to Evaluate the Development and Function of Various Proteins in Keratinocytes and Other Epidermal and Dermal Cells

(5) Start Date: 1991 (6) Est Compl Date: 1993

(7) Principal Investigator: Scott Bennion, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Dermatology (10) Associate Investigators: James Fitzpatrick, LTC, MC
(11) Key Words: keratinocytes Loren Golitz, MD, UCHSC
monoclonal antibodies Ron Jackson, CPT, MS
Don Mercill, DAC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Through the use of cultured human epidermal cells this study will determine the specificity of monoclonal antibodies for certain skin protein antigens implicated in skin tumors and whether the expression of these antigens changes with alterations in the cell culture environment such as density of cells and exposure to UV light.

(16) Technical Approach: This study involves a number of highly technical laboratory procedures as outlined in the protocol.

(17) Progress: Several preliminary staining experiments have been done. CPT Mary Mather-Mondrey is currently working on the project during my absence.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/135A (3) Status: Ongoing

(4) Title: Induction of Clinical Lesions in XID/Beige/Nude Mice
Using Various Factors

(5) Start Date: 1991

(6) Est Compl Date: 1991

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dermatology

(10) Associate Investigators:

Lela Lee, MD, UCHSC

(11) Key Words:
lupus erythematosus

Ronald Jackson, PhD
Donald Mercill, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To develop a working animal model of subcutaneous lupus erythematosus; to induce clinical and histological lesions of SCLE in the beige/nude/XID mouse; to characterize the lesions produced histologically and immunologically.

(16) Technical Approach: Per protocol approved by LACUC 18 Jul 91.

(17) Progress: 40 nude mice were grafted with human skin. Analysis of data and tissue is still in progress. Principal investigator temporarily assigned to Kuwait.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/136 (3) Status: Ongoing

(4) Title: I. A Clinical and Radiographic Comparison of Parenteral Gold Versus Parenteral Methotrexate in the Treatment of Early Rheumatoid Arthritis. II. The Effect of Low-Dose Methotrexate on Bone Metabolism and Bone Density

(5) Start Date: 1991 (6) Est Compl Date: 1994

(7) Principal Investigator: Daniel Battafarano, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Rheumatology (10) Associate Investigators:
Kimberly May, CPT, MC
Sterling West, LTC, MC
Michael McDermott, LTC, MC
Paul Miller, MD, UCHSC

(11) Key Words:
arthritis
methotrexate
bone density

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Part I: a) to compare the clinical efficacy of parenteral gold and parenteral methotrexate in the treatment of rheumatoid arthritis; b) to compare radiographic progression of RA in these two treatment groups. Part II: to evaluate the effect of low-dose methotrexate on bone metabolism and bone density.

(16) Technical Approach: Patients will be randomly assigned to receive either intramuscular methotrexate or gold. Laboratory tests and bone densitometries will be performed periodically to monitor rheumatoid arthritis and drug therapy.

(17) Progress: None to date. No funding available for this study at this time. The study will be submitted for a 1992 Arthritis Foundation Research Award and also to FACT for assistance but have not received any feedback.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/137 (3) Status: Ongoing

(4) Title: Effect of Specific Immunotherapy on Peripheral Lymphocyte Intracellular Adhesion Molecules (ICAM 1)

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
Allan Au, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:

(11) Key Words:
immunotherapy
lymphocytes
ICAM 1

T. Ray Vaughan, MAJ, MC
Richard Weber, COL, MC
Anthony Henry, LTC, MC
Matthew Cary, CPT, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul, b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if there is up regulation or down regulation of cell surface ICAM molecules on circulating T lymphocytes when comparing patients on successful specific immunotherapy compared to age and sex matched controls.

(16) Technical Approach: This study will use the cytofluorometric technique to measure changes in the relative number of cell surface ICAM molecules comparing patients on successful immunotherapy to controls.

(17) Progress: Thus far 31 patients entered into the study. No conclusions can be formed from the data yet. We are currently awaiting the arrival of the new allergy fellows for continuance of the protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/138A (3) Status: Completed

(4) Title: Effects of Beta-blockers on Intracellular Cyclic Nucleotide Generation in Guinea Pig (Cavia porcellus) Airway Smooth Muscle

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Michael O'Connell, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Allergy (10) Associate Investigators: Anthony Henry, LTC, MC

(11) Key Words: beta-blockers T. Ray Vaughan, MAJ, MC

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 7
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: Airway smooth muscle treated with beta-blocker will show significantly less generation of cyclic AMP than control (untreated) smooth muscle when constricted with histamine or relaxed with albuterol.

(16) Technical Approach: Per protocol approved by LACUC on 15 Aug 91.

(17) Progress: As of 30 Sep 91 a total of 28 experiments utilizing seven guinea pigs have been performed. Tracheal tissue from each experiment has been frozen and stored at -70° C awaiting arrival of the cyclic AMP assay kits from the manufacturer. Once these kits have arrived at FAMC, we can proceed with the cyclic AMP measurements and analyze the data. The study was completed FY 92.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/139 (3) Status: Ongoing

(4) Title: SWOG 9045 Evaluation of Quality of Life in Patients with
Advanced Colorectal Cancer Enrolled on SWOG 8905

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/140 (3) Status: Ongoing

(4) Title: SWOG 9040 Intergroup Rectal Adjuvant Protocol, A Phase III Study

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Hema/Oncol

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the SWOG group protocols.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 91/141 (3) **Status:** Ongoing

(4) **Title:** SWOG 9009 Pilot Study for Analysis of Lymphocyte Subsets
and Natural Killer Activity after Treatment with
Levamisole

(5) **Start Date:** 1991 (6) **Est Compl Date:**

(7) **Principal Investigator:** Thomas Cosgriff, COL, MC (8) **Facility:** FAMC

(9) **Dept/Svc:** Hema/Oncol (10) **Associate Investigators:**

(11) **Key Words:**

(12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** _____ b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** 1
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To participate in the SWOG group protocols.

(16) **Technical Approach:** See protocol.

(17) **Progress:** No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/142 (3) Status: Ongoing

(4) Title: A Multi-Center, Double-Blind, Double-Dummy, Placebo-Controlled, Group-Comparative Study of the Safety and Effectiveness of Four Dose-Levels of Tipredane as Compared to Belcomethasone Dipropionate in the Treatment of Adults with Moderate Asthma. FISIONS Study No. 1900-2209

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
Richard Weber, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Allergy

(10) Associate Investigators:

(11) Key Words:
tipredane
investigational new drug

T. Ray Vaughan, MAJ, MC
David Goodman, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Based on efficacy, laboratory and adverse event data, the overall objective of this study will be to determine the optimum doses, in relation to safety and efficacy, of tipredane with which to conduct future clinical trials.

(16) Technical Approach: Study centers will enroll 30 subjects each for a total of 540 patients to complete this investigational new drug trial sponsored by Fisons.

(17) Progress: Five subjects enrolled.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/143 (3) Status: Ongoing
-
- (4) Title: A Multi-Center Randomized Comparative Trial Evaluating Safety and Efficacy of Monopolar Versus Bipolar Polypectomy Snares
-
- (5) Start Date: 1991 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Peter McNally, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Gastroenterology (10) Associate Investigators:
Robert Sudduth, MAJ, MC
John Meier, MAJ, MC
Frank Jahns, MAJ, MC
Dirk Davis, CPT, MC
Stephen Freeman, COL, MC
-
- (11) Key Words:
polypectomy
snares
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 250
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To compare the efficacy, generator settings, and complication rates in the use of the monopolar versus bipolar polypectomy snares for the removal of colonic polyps.
-
- (16) Technical Approach: Large sessile and pedunculated polyps will be lassoed with either the wire snare or the Bi-Snare in a standard fashion. For the Bi-Snare, electrical current will be applied using current settings of CUT 7 wats & COAG 6 with BLENB 2 on FORCE 1B; 1.0 CUT & 1.5 COAG blended-cut on the SSEL2. For the monopolar, electrical current will be applied using standard settings of coagulation 3 and cut 0, at 1 to 2 second pulses.
-
- (17) Progress: To date 250 patients enrolled; 135 underwent randomized snar polypectomy; complications none to date. Preliminary data presented at ADW, May 92. Followup report accepted for presentation at Am. Coll. Gastro. 26-28 Oct 92.

Publications and Presentations: Two presentations.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/144 (3) Status: Ongoing

(4) Title: Effect of Glucose on Residual Renal Function in Peritoneal Dialysis

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: James Hasbargen, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Neph (10) Associate Investigators: Barbara Hasbargen, RN, DAC
Edwin Fortenbery, MAJ, MC

(11) Key Words: peritoneal dialysis

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To assess difference in residual renal function in patients with and without intraperitoneal glucose.

(16) Technical Approach: The studies will be done after the patients (6-8) utilize the standard peritoneal dialysate which contains 1.5-4.25% glucose, and the other study will be done utilizing peritoneal dialysate which is identical with the exception of glucose. The patients will be on the non-glucose containing dialysate for a period of 24 hrs prior to doing the nuclear medicine study. The order in which the residual renal function determinations are performed will be in a randomized fashion.

(17) Progress: Recently approved study. Three patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/145 (3) Status: Ongoing
-
- (4) Title: The Effect of Parathyroid Hormone versus Phosphate on Osteoblast Function; and the Effect of Age on Stimulated Osteoblast Function
-
- (5) Start Date: 1991 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Jan Perloff, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Endocrine (10) Associate Investigators: Michael McDermott, LTC, MC
-
- (11) Key Words:
osteoblast
parathyroid hormone
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine if Neutraphos is helpful in making bones stronger or if another synthetic hormone is necessary to stimulate the bones to be stronger. The study is also trying to determine if age has an effect on the ability to stimulate normal bone formation and strength.
-
- (16) Technical Approach: Prospective study using subjects as their own controls using synthetic human PTH in a dose preset by the pilot trial subcutaneously q day for 3 days followed by a washout period of 2 weeks, then Neutrophos 500 mg po 4 times per day for 3 days.
-
- (17) Progress: Needs Re-evaluation. Path impact pending. PI submitted for IND, PI PCS'd. No report.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/146 (3) Status: Ongoing

(4) Title: Work of Breathing as a Predictor of Failure to Wean From Mechanical Ventilation in Patients with Severe Chronic Obstructive Pulmonary Disease

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Jack DePriest, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Med/MICU (10) Associate Investigators:

(11) Key Words:
COPD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To prospectively determine whether measuring the work of breathing by metabolic cart in patients with severe COPD can be useful in predicting their ability to sustain spontaneous respirations. It will also validate or determine new cutoff values for the CROP score and f/Vt ratios.

(16) Technical Approach: Just prior to extubation the patient will have his work of breathing measured by the metabolic cart. The patient is then extubated as planned. The patient will then be followed to see if he tolerates extubation or develops respiratory failure, requiring reintubation.

(17) Progress: No progress, the required apparatus is still not available, although MRDC funding was approved.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/147 (3) Status: Ongoing
-
- (4) Title: SWOG 8730 Evaluation of Amonafide in Esophageal Cancer
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the most effective treatment of cancer.
- (16) Technical Approach: Per NCI-approved protocol.
- (17) Progress: No patients enrolled to date.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/148 (3) Status: Ongoing

(4) Title: SWOG 8911 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective cancer treatment.

(16) Technical Approach: Per NCI-approved protocol.

(17) Progress: No patients enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/149 (3) Status: Ongoing
-
- (4) Title: SWOG 8936 Evaluation of Piroxantrone in Refractory Carcinoma of the Breast, Phase II.
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the most effective cancer treatment.
- (16) Technical Approach: Per NCI-approved protocol.
- (17) Progress: No patients enrolled to date.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/150 (3) Status: Ongoing
-
- (4) Title: SWOG 9007 Cytogenetic Studies in Leukemia Patients, Ancillary
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the most effective treatment of cancer.
- (16) Technical Approach: Per NCI-approved protocol.
- (17) Progress: Patient failed induction therapy, patient has died.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/151 (3) Status: Ongoing

(4) Title: SWOG 9108 A Phase III Comparison of Fludarabine Phosphate vs Chlorambucil vs Fludarabine Phosphate Plus Chlorambucil in Previously Untreated B-Cell Chronic Lymphocytic Leukemia

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Med/Hem-Onc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective treatment of cancer.

(16) Technical Approach: Per protocol.

(17) Progress: No patient enrolled to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/100. (3) Status: Ongoing

(4) Title: The Efficacy and Safety of Misoprostol in the Prevention of NSAID-induced GI Complications

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Sterling West, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Rheumatology

(10) Associate Investigators

(11) Key Words:
misoprostol
investigational new drug

Ruth Hugler, Rn

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 26

d. Total Number of Subjects Enrolled to Date: 26

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". NONE

(15) Study Objective: To investigate the efficacy and safety of misoprostol for a new indication, the prevention of gastrointestinal ulcer complications in patients with rheumatoid arthritis who are taking non-steroidal anti-inflammatory drugs for their arthritis.

(16) Technical Approach: Enroll 30 rheumatoid arthritis patients over the age of 60 on NSAIDS. Subjects will receive active drug, misoprostol, or placebo for six months in addition to their standard medication for rheumatoid arthritis. The study is double-blinded, and evaluation criteria is the comparison of the rate of GI events between the two groups.

(17) Progress: We have enrolled 26 patients into the study. Of these 6 patients have completed the entire study, 4 patients stopped study medication due to side effects, and 16 patients are continuing on at various stages of the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/101 (3) Status: Ongoing

(4) Title: SWOG 8913 Evaluation of Mebarone in Malignant Melanoma,
Phase II

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/102 (3) Status: Ongoing

(4) Title: SWOG 8956 A Phase II Study of Cisplatin and 5-FU
Infusion for Treatment of Advanced and/or Recurrent
Metastatic Carcinoma of the Urinary Bladder

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG protocol in the study
of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/103 (3) Status: Ongoing

(4) Title: SWOG 9016 Study of External Brain Irradiation and
Cisplatin/BCNU Followed by BCNU for the Treatment of
Primary Malignant Brain Tumors, Phase II

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG protocol in the study
of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/104 (3) Status: Ongoing

(4) Title: C91-180 Phase III Randomized Controlled Trial Comparing the Efficacy of Combination Therapy with 5-Fluorouracil and Leucovorin Against the Efficacy of Combination Therapy with 5-Fluorouracil and Intron A in the Treatment of Metastatic Colorectal Cancer

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/105 (3) Status: Ongoing

(4) Title: Bi-Bx Removal of "Hard to Reach" Colon Polyps: A Pilot Evaluation of a New Polypectomy Technique

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Peter McNally, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro

(10) Associate Investigators

(11) Key Words:
colon polyps
polypectomy

Dr. Suddeth
Ms. DeAngalis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 9
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the utility of a new biopsy technique.

(16) Technical Approach: Prospective evaluation with followup for technical success and complications.

(17) Progress: Nine patients enrolled to date, 12 polypectomies, no complications.

Publications: Am J Gastro 87:1329, 1992
Presentations: Will be presented in FY 93

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/106A (3) Status: Terminated

(4) Title: The Efficacy of an ICU Dedicated Ultrasound Unit in
Confirming Tracheal Intubation

(5) Start Date: Nov 1991

(6) Est Compl Date: Jan 92

(7) Principal Investigator:
Jack DePriest, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if one could ultrasonographically confirm tracheal intubation.

(16) Technical Approach: The ultrasound operator, who doesn't know where the tube was placed, will try to determine the location by ultrasound.

(17) Progress: The ultrasound unit was not able to reliably confirm endotracheal tube location. The study was terminated after attempting one goat and one ferret.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/107 (3) Status: Ongoing

(4) Title: Treatment of Graves' Disease with Cholestyramine

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Arnold Asp, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

(11) Key Words:
hyperthyroidism
cholestyramine

Michael McDermott, LTC, MC
Gregory B. Hughes, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 2

d. Total Number of Subjects Enrolled to Date: 2

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the efficacy of adding cholestyramine to conventional antithyroid drug therapy in rapidly achieving a euthyroid state in patients with active hyperthyroid graves disease.

(16) Technical Approach: Parallel two-group repeated measures design in which half the patients receive traditional therapy with methimazole and atenolol, while the other half receive methimazole and atenolol plus cholestyramine for a period of four weeks.

(17) Progress: Two patients enrolled at FAMC. Seven patients enrolled at WRAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/108 (3) Status: Completed

(4) Title: The Occurrence of Positive Immunofluorescence in the
Dermo-Epidermal Junction of Sun-Exposed Skin of Normal
Adults

(5) Start Date: 1992

(6) Est Compl Date: 1992

(7) Principal Investigator:
Ann Leibold, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Dermatology

(10) Associate Investigators

Milton Sclene, LTC, MC

(11) Key Words:
immunofluorescence

Scott Bennion, LTC, MC

Kathleen David-Bajar, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 41
d. Total Number of Subjects Enrolled to Date: 41
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To determine whether sun-exposure causes lupus-
like immunofluorescence at the dermo-epidermal junction.

(16) Technical Approach: Skin samples are taken adjacent to skin cancer
excision sites and examined for immunofluorescence.

(17) Progress: The study has been completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/109 (3) Status: Ongoing

(4) Title: Characterization of a Human Thyroid Cancer Cell Line

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:

(8) Facility: FAMC

Bill Georgitis, MAJ, MC

(9) Dept of MED/Endocrine

(10) Associate Investigators

(11) Key Words:
cell line thyroid
thyroid cancer

Tony Gutierrez
Donald Mercill

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV____ b. Review Results:____
c. Number of Subjects Enrolled During Reporting Period:____
d. Total Number of Subjects Enrolled to Date:____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Identify and characterize an immortal thyroid cancer cell line in terms of degree of differentiation and thyroid cell/molecular biology.

(16) Technical Approach: The cells will be studied using a variety of techniques including immunohisto chemistry, molecular biology and radioisotope methods.

(17) Progress: Positive immunohistochemical staining for thyroglobulin has been found. Attempts to reverse transcribe thyroglobulin cDNA from thyroglobulin message are under way.

Presentations:

1. Society of Uniformed Endocrinologists meeting, (poster) June 1992.
2. American Thyroid Association (poster) September 1992.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/110A (3) Status: Terminated

(4) Title: Effects of Glucagon on Guinea Pig Cavia porcellus Airway Smooth Muscle

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Paul Schkade, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Allergy

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

N/A

(16) Technical Approach:

N/A

(17) Progress: This study was never started, PI terminated the study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/111 (3) Status: Ongoing

(4) Title: The Effect of Exogenous Thyrotropin Releasing Hormone on Plasma Atrial Natriuretic Peptide

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Michael McDermott, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 6

d. Total Number of Subjects Enrolled to Date: 6

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if TRH administration has any effect on serum levels of anpand, if so, whether this is a direct effect or due to the pressor response to TRH.

(16) Technical Approach: Various doses of TRH are given to normal volunteers on differencnt days. After TRH administration blood is drawn for ANP levels and blood pressure and pulse are monitored continually.

(17) Progress: 6 subjects have been tested with one dose and no ANA response occured despite an increase in blood pressure. We are currenlty rechecking the samples and determining the performance characteristics of the assay kit.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/112 (3) Status: Terminated

(4) Title: An Open Pilot Study to Investigate the Effects of
Intravenous Anaritide Acetate Alone and With Mannitol
in the Treatment of Acute Renal Failure

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
James Hasbargen, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Nephrology

(10) Associate Investigators

(11) Key Words:
acute renal failure

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: No progress, terminated study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/113 (3) Status: Ongoing

(4) Title: Cyclosporine Treatment of Idiopathic Chronic Active Hepatitis

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Kenneth Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Multicenter trial to evaluate potential for cyclosporin as a therapeutic agent in steroid resistant autoimmune hepatitis.

(16) Technical Approach: Open label therapeutic trial of cyclosporin in patients with idiopathic chronic active hepatitis that is resistant to steroids and/or in patients who cannot tolerate standard immunosuppression methods.

(17) Progress: To date 6 patients with chronic active hepatitis have been enrolled with 4 of these at FAMC. All patients seemed to demonstrate a response. Among patients who completed at least 16 weeks of therapy, 3/4 were classified as responders as defined by normalization or near normalization of ALT. One hypertensive patient continued severe hypertension on this therapy. Creatinine rose in one patient but this was concurrent with amphotericin B use for Sporothrix infection that was present prior to initiation of therapy.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/114 (3) Status: Ongoing

(4) Title: Household Transmission of Hepatitis C Virus in Military Populations

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Kenneth Sherman, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 52

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Multicenter trial to determine prospective incidence of hepatitis C in family members of index cases.

(16) Technical Approach: Demographic/risk questionnaire with serial serum collection and testing for hepatitis C nucleic acid and antibodies.

(17) Progress: To date 14 patients with chronic active hepatitis attributable to viral hepatitis C have been enrolled at FAMC. Additionally, 38 family members of the index cases have agreed to participate. There have been no adverse events associated with this protocol.

Publications and Presentations: American Association for Liver Disease National Meeting, November, 1992.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/115A (3) Status: Completed

(4) Title: The Effects of Physiologic PEEP (Positive End Expiratory Pressure) on Transglottic Pressures and the Generation of Intrapleural Pressures

(5) Start Date: 1992

(6) Est Compl Date: 1992

**(7) Principal Investigator:
Marin Kollef, MAJ, MC**

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

**(10) Associate Investigators
Dr. McCormack**

**(11) Key Words:
sheep
acute lung injury**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: JAN b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: To develop an animal model to assess acute lung injury for further study.

(16) Technical Approach: Placement of ET tube to monitor pulmonary pressure after IV injection of organic acid to a heavily sedated sheep.

(17) Progress: Our results suggest that (1) partial bypass of the upper airway may be associated with a decrease in the development in the development of subglottic pressures, and (2) respiratory timing and pulmonary gas exchange are influenced by the upper airway during acute lung injury.

Publications and Presentations: Kollef MH, McCormack MT, Banks RE: The Effect of Partial Upper-Airway Bypass on Subglottic Pressure during Acute Lung Injury in Sheep. Respir Care Oct 92, vol 37, no 10, p1166-1174.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/116 (3) Status: Ongoing

(4) Title: Early Detection of Second Primary Lung Cancers by Sputum Cytology Immunostaining

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Jerry Pluss, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 9

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Study usefulness of immunostaining cytology compared to regular sputum cytology, cxr and examination in the detection of recurrent lung cancer. This very high risk population is being used instead of cigarette smokers to obtain data on a smaller group of patients in a shorter time frame.

(16) Technical Approach: Yearly examination of high risk population that develops lung cancer. Using history, physical examination, cxr, induced sputums, non-induced sputums and bronchoscopy to evaluate cytologic methods (routine techniques, immuno staining techniques and other tumor markers).

(17) Progress: 9 patients have been enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 92/117 (3) Status: Ongoing
-
- (4) Title: A Comparison of the Efficacy, Safety and Tolerance of
Ceftibuten (SCH 39720) 300 mg Given BID and Augmentin
500 mg Given TID in the Treatment of Community Acquired
Pneumonia
Schering-Plough Research Protocol C91-248-00, IND # 30,303
-
- (5) Start Date: 1992 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Daniel Ouellette, MAJ, MC (8) Facility: FAMC
-
- (9) Dept of MED/Pul. Dis. (10) Associate Investigators
-
- (11) Key Words: Dr. David Kristo
Dr. J.F. Turner
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e". GI disturbances
-
- (15) Study Objective: To compare the efficacy, safety, and tolerance of
high dose ceftibuten (Sch 39720) 300mg BID with that of augmentin 500mg
TID in the treatment of pneumonia.
- (16) Technical Approach: Patients presenting to the pulmonary clinic
with pneumonia are randomized to ceftibuten or augmentin after meeting
study entrance criteria and signing a informed consent.
- (17) Progress: Four patients enrolled 4/92, last one 8/28/92. 3 -
terminated early because entrance criteria not met (i.e., sensitivities,
bacteriology results). 1- dropped due to treatment failure.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/118 (3) Status: Ongoing

(4) Title: A Comparison of the Efficacy, Safety, and Tolerance of Ceftibuten (SCH 39720) 400mg (1 x400 mg capsule) in the Fed and Fasted State and Augmentin Amoxicillin/Clavulanate 1.5 gm (1 x 500 mg tablet TID) in the Fed State in the Treatment of Acute Exacerbations of Chronic Bronchitis Schering-Plough Research Protocol (C90-038-00, IND #30,303

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Daniel Ouellette, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

(10) Associate Investigators

(11) Key Words:

Dr. David Kristo
Dr. J.F. Turner

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 14

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". Pt. hospitalized with renal failure. Patient died as a result of intraabdominal sepsis (result of perforated gall bladder) ; GI Disturbances, nausea, etc.

(15) Study Objective: To compare the efficacy, safety and primarily the GI tolerance of once-daily ceftibuten in both the fed and fasted state with that of augmentin given TID in the fed state in the treatment of acute exacerbations of chronic bronchitis in adults.

(16) Technical Approach: Patients presenting to the pulmonary clinic with acute exacerbation of chronic bronchitis are randomized to ceftibute or augmentin.

(17) Progress: Sinc 2/92, 14 patients have been enrolled, 9 patients completed, 2 patients dropped due to treatment failure; 3 pts terminated early due to entrance criteria not met and one adverse event.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/119 (3) Status: Completed

(4) Title: The Personal Economics of Intensive Care

(5) Start Date: 1992

(6) Est Compl Date: 1992

(7) Principal Investigator:
J.F. Turner, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pul. Dis.

(10) Associate Investigators

(11) Key Words:

micu, cost of care

dollar offset decision

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 102

d. Total Number of Subjects Enrolled to Date: 102

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if personnel indemnity bears a relation to whether MICU care is considered or not.

(16) Technical Approach: Retrospective review of charts. Telephone questionnaires.

(17) Progress: Data collection completed.

Publications and Presentations: Poster presentation: International American Thoracic Society Meeting, May 1992. Paper being rewritten for possible publication in office.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/120 (3) Status: Ongoing

(4) Title: Prevalence of Gluten Sensitive Enteropathy in Patients
with Insulin Dependent Diabetes Mellitus

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Peter McNally, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:
celiae disease
diabetes

Dr. Davis
Dr. Merenich
Kenneth Sherman, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Prospective evaluation of the prevalence of GSE
among type I IDDM patients.

(16) Technical Approach: Evaluation of the prevalence of GSE among type
I IDDM patients.

(17) Progress: Have just procured the AEM assay kit. Hope to be
recruiting patients in October.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/121 (3) Status: Terminated

(4) Title: Diverticulosis of the Gastrointestinal Tract in Patients
with Autosomal Dominant Polycystic Kidney Disease

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Dirk Davis, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators
John Meier, MAJ, MC
(11) Key Words: James Hasbargen, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: As per the title to correlate this with clinical
parameters.

(16) Technical Approach: Measurement of multiple clinical parameters.

(17) Progress: The original Principal Investigator was unable to meet
IRC stipulations for approval due to health problems. By the time a new
PI was appointed, UCHSC completed the same study.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/122 (3) Status: Ongoing

(4) Title: SWOG 9061 A Phase III Study of Conventional Adjuvant Chemotherapy versus High Dose Chemotherapy and Autologous Bone Marrow Transplantation as Adjuvant Intensification Therapy Following Conventional Adjuvant Chemotherapy in Patients with Stage II and III Breast Cancer at High Risk of Recurrence

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Thomas Cosgriff, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 92/123 (3) Status: Ongoing
-
- (4) Title: A Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Effect of Quinapril in Reducing Ischemic Events During a 3-Year Follow-up in Patients Post Intervention: QUIET (Quinapril Ischemic Event Trial). (IND) Parke-Davis Protocol 906-370
-
- (5) Start Date: 1992 (6) Est Compl Date: 1996
-
- (7) Principal Investigator: Richard Davis, COL, MC (8) Facility: FAMC
-
- (9) Dept of MED/Cardiology (10) Associate Investigators
Robert Cameron, LTC, MC
Peter Bigham, MAJ, MC
-
- (11) Key Words:
investigational new drug
ischemia
quinapril
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: MAR/Sep b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 11
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To test the effectiveness of an investigational new drug, quinapril, to prevent ischemic events post angioplasty or atherectomy.
-
- (16) Technical Approach: Multi-center international trial---double-blind, randomized, placebo-controlled. Approximately 75 patients will be enrolled at FAMC and followed for a three-year period.
-
- (17) Progress: It appears from data gathered at other institutions where subjects have been enrolled for some time that the placebo group requires recatheterization, while treadmills are negative on the active drug group.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/124 (3) Status: Ongoing

(4) Title: Frequency of Lovastatin and Pravastatin Induced ANA Antibodies and Antibody Identity

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: Jan Perloff, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Endocrine (10) Associate Investigators

(11) Key Words: lovastatin pravastatin antinuclear antibodies Sterling West, COL, MC Michael McDermott, LTC, MC

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: MAR b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 100
d. Total Number of Subjects Enrolled to Date: 100
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: To determine the incidence of ANA positivity in patients taking Hmb Coa reductase inhibitors.

(16) Technical Approach: Cross-sectional - Patients taking lovastatin will have ANA determined and if positive they will be characterized as to the antibody type. Prospective: Patients started on pravastatin will have ANA determined before and periodically after being started on pravastatin.

(17) Progress: 100 patients on lovastatin have been tested cross-sectionally; 5 have positive ANA's and the antibody type is now being further delienated in an outside collaborating lab. No patients on pravastatin have been tested yet.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/125 (3) Status: Ongoing

(4) Title: The Relationship Between High Resolution Electro-cardiography and Ventricular Ectopy in Hypertensive Patients with Left Ventricular Hypertrophy: A Pilot Study

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Richard Shea, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators

(11) Key Words:

Mark Dorogy, MD
Aryo Oopick, MD
William Highfill, MD
David Boike, MD

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 28

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To establish the relationship between echocardiographically determined LV mass, ectopy by Holter monitor, and abnormalities of the SAEIIG on hypertensive patients with LVH.

(16) Technical Approach: Prospective study of hypertensive patients. We obtain echo, Holter, and SAEIIG data and analyze in context of LV Mass vs percent of ectopy vs abnormal SAEIIG criteria.

(17) Progress: Enrollment continues at slower than predicted rate. Initial data suggests no relationship between LV mass and SAEIIG data, but more patients are needed. Negative results are still significant. Study design appears good. Results comparable to data available in literature.

Publications and Presentations: Interim results presented 05 Nov 92 at Army ACP meeting, Cardiology Section, by M. Dorogy.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/126 (3) Status: Ongoing

(4) Title: Study of the Effect of Oral Extended-Release Nitroglycerin Capsules in Patients with Angina Pectoris: KV NTG versus Placebo

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
William Highfill, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Cardiology

(10) Associate Investigators

(11) Key Words:
nitroglycerin
angina pectoris

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Confirm results of previous trial of once a day long-acting oral NTG and establish that there is no clinically significant rebound effect from long-acting oral NTG.

(16) Technical Approach: Double-blind, two way crossover study using treadmill stress testing in ambulatory patients with chronic stable angina pectoris.

(17) Progress: Slow - about 10 patients have been screened. Only one patient was completely satisfactory, and has completed the study protocol and is back on his prior meds. He experienced no adverse effects. Recruitment is ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/127 (3) Status: Ongoing

(4) Title: A Phase III, Randomized Comparative Trial of ZDV versus ZDV plus ddI versus ZDV plus ddC in HIV-Infected Patients (NUCOMBO)

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
William R. Byrne, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Inf. Dis.

(10) Associate Investigators

(11) Key Words:

Robert Gates, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 5

d. Total Number of Subjects Enrolled to Date: 5

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if combining ddI or ddC with ZDV is more effective than ZDV alone in controlling HIV.

(16) Technical Approach: See protocol.

(17) Progress: To early to compile any data on this study.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/128 (3) Status: Terminated

**(4) Title: Subcutaneous Administration of Octreotide Acetate
(Sandostatin) for the Treatment of Relapsed Small Cell
Lung Cancer**

(5) Start Date: 1992

(6) Est Compl Date:

**(7) Principal Investigator:
Daniel Tell, LTC, MC**

(8) Facility: FAMC

(9) Dept of MED/Hem/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

**e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".**

(15) Study Objective:

(16) Technical Approach:

**(17) Progress: Study remains unfunded, recommend the study be
terminated.**

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 92/129 (3) Status: Ongoing
-
- (4) Title: Randomized Comparison of Radiation Versus Radiation Plus Continuous 5-Fluorouracil Infusion for Palliation of Bone Metastases: Phase II Study
-
- (5) Start Date: 1992 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC
-
- (9) Dept of MED/Hem/Onc (10) Associate Investigators
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 4
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To determine whether better palliation of bone metastases and improved local control of tumor results from radiation plus continuous 5-Fu infusion compared to radiation alone.
-
- (16) Technical Approach: Enroll at total of 42 patients, with 21 patients in each treatment group.
-
- (17) Progress: Four patients enrolled, 3 of which were randomized to radiation alone. All patients are alive; two patients are still receiving treatment. No conclusions about the treatment can be made.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/130 (3) Status: Ongoing

(4) Title: Antigen-Specific Immunoglobulin and Lymphocyte Responses
in Systemic Lupus Erythematosus Patients Following
Immunization with Three Clinically Relevant Vaccines

(5) Start Date: 1992 (6) Est Compl Date: Feb 93

(7) Principal Investigator: (8) Facility: FAMC
Nicholas Battafarano, MAJ, MC

(9) Dept of MED/Allergy (10) Associate Investigators
Michael Lieberman, LTC, MC
Raymond Enzenauer, MAJ, MC
Daniel F. Battafarano, MAJ, MC
Lawrence Larson, MAJ, MC
David Goodman, COL, MC

(11) Key Words:
lupus
systemic lupus erythematosus
immunizations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 31
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Determine immunization responses in systemic
lupus, erythematosus patients to develop practical immunization
prescriptions for these patients.

(16) Technical Approach: Pre-immunization: Clinical evaluation
immunoglobulin levels, lymphocyte responses; Immunize with pneumococcal,
H. Influenza and test toxoid immunizations; Post-immunization: Clinical
evaluation immunoglobulin levels, lymphocytes responses.

(17) Progress: Excellent - 25/27 patients invited have agreed to
participate, 6 enrolled in test validation group, local injection
inflammation has occurred as expected in a few patients. No difference
in either group and all easily treated with tylenol, aspirin or NSAIDS.
Symptoms sore, red area at site of injection.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/131 (3) Status: Ongoing

(4) Title: Determination of Indirect Immunofluorescence Results in
Bullous Pemphigoid and Pemphigus

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Kathleen David-Bajar, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Dermatology (10) Associate Investigators

Scott Bennion, COL, MC

(11) Key Words: Ronald Jackson, DCI

skin splitting for immunofluorescence

basement membrane zone of skin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the ultrastructural level of splitting of neonatal and adult skin using NaCl and EDTA.

(16) Technical Approach: Neonatal foreskins, and adult skin removed during surgery, which would normally be discarded will be split with standard methods, and the level of splitting will be examined using structural landmarks, and standardized antibodies.

(17) Progress: Immunogold methods are not yet worked out. The electron microscopy technician has been separated from the Army. A new EM technician is not available.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/132 (3) Status: Ongoing

(4) Title: Aspects of Alveolar Macrophage Function During HIV Infection

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Daniel Ouellette, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Pulmonary Disease (10) Associate Investigators

(11) Key Words:

George M. Giacoppe, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Investigate the role of intracellular adhesion molecules in the development of HIV infection.

(16) Technical Approach: Measure levels of ICAM-1 in BAL fluid in HIV infected patients and in controls bronchoscoped for other reasons.

(17) Progress: In process of refining assay techniques in BAL fluid. Recruiting HIV patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/133 (3) Status: Ongoing

(4) Title: Patterns of Respiratory Diastole

(5) Start Date: 1992 (6) Est Compl Date:
1 9 9 3

(7) Principal Investigator: (8) Facility: FAMC
Michael Perry, COL, MC

(9) Dept of MED/Pul.Dis. (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To ascertain the airflow in COPD patients at end expiration.

(16) Technical Approach: Patients will breath through mask fitted with penumotach while resting in reclining chair.

(17) Progress: No progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/134 (3) Status: Ongoing

(4) Title: Deadspace Interactions in Emphysema

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Michael Perry, COL, MC

(8) Facility: FAMC

(9) Dept of MED/Pul.Dis.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: June b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate atypical relationship of physiologic and anatomic deadspace in emphysema.

(16) Technical Approach: Mechanical deadspace added and physiologic deadspace monitored with arterial blood gases.

(17) Progress: No progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/135 (3) Status: Ongoing

(4) Title: Determination of Microbial Organisms in Russian Thistle Pollen and Their Effects on Protein Extraction from the Pollen

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Lawrence Larsen, MAJ, MC

(8) Facility: FAMC

(9) Dept of MED/Allergy

(10) Associate Investigators

(11) Key Words:
pollen
Russian thistle
extraction
microbes

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: June b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: NA
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine best extraction method for Russian thistle pollen by examining bacterial content of pollen and effects of antibacterial method.

(16) Technical Approach: Extract aliquote of pollen at various temperatures, for various timer, with different buffers and antibacterial agents and protease inhibitors. Extracts examined for total protein and analyzed on PAGE and compared.

(17) Progress: Have finished all extraction under various conditions. Have completed PAGE analysis. Pending western blot analysis. Have completed total protein determination.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/136 (3) Status: Completed

(4) Title: Prevalence of Hepatitis C Antibody in Patients with
Thyroid Disease

(5) Start Date: 1992

(6) Est Compl Date: 1992

(7) Principal Investigator:
Dirk Davis, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators
Michael McDermott, LTC, MC
Pari Morse, B.S., DAC
Kenneth Sherman, MAJ, MC

(11) Key Words:
hepatitis C
thyroid disease

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: July b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To determine if the seroprevalence of antibody to
hepatitis C is greater in patients with proven thyroid disease than in
the general population, or in patients with other non-thyroid endocrine
disease.

(16) Technical Approach: Retrospective study of serum bank.

(17) Progress: Serum of 88 patients were studied. One was positive.
Higher rate than expected but within the bounds of a chance occurrence.
A prospective study is planned.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/137 (3) Status: Completed

(4) Title: SWOG 8991 - A Phase III Study of Cisplatin Plus Etoposide Combined with Standard Fractionation Thoracic Radiotherapy vs Cisplatin Plus Etoposide Combined with Multiple Daily Fractionated Thoracic Radiotherapy for Limited Stage Small Cell Lung Cancer

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: July____ b. Review Results:____
c. Number of Subjects Enrolled During Reporting Period:____
d. Total Number of Subjects Enrolled to Date:____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group protocol in the study of malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Protocol was closed before any patients were enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/138 (3) Status: Ongoing

(4) Title: A Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study of the Use of Weekly Azithromycin as Prophylaxis Against the Development of Mycobacterium Avium Complex (MAC) Disease in HIV-Infected People

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: W.R. Byrne, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators

(11) Key Words: Robert Gates, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUG _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the safety and efficacy of oral azithromycin administered once a week in the prevention of disseminated MAC in severely immunocompromised HIV infected patients with a CD4 cell count of <100/mm.

(16) Technical Approach: See protocol.

(17) Progress: None; awaiting receipt of study drug, final onsite visit by Pfizer.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/139 (3) Status: Ongoing

(4) Title: Phase I Study of Alferon N Injection in Persons with Asymptomatic Human Immunodeficiency Virus (HIV) Infection

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: W.R. Byrne, LTC, MC (8) Facility: FAMC

(9) Dept of MED/Inf.Dis. (10) Associate Investigators Robert Gates, LTC, MC

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUG b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the safety and tolerance of subcutaneous injections of natural interferon-alpha (IFN) in asymptomatic HIV-positive persons and to record its effect on the HIV virus in these individuals.

(16) Technical Approach: See protocol

(17) Progress: New study, no progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/140 (3) Status: Ongoing

(4) Title: The Detection of Antibodies to Helicobacter Pylori in
Samples Obtained with the OraSure Oral Specimen
Collection Device

(5) Start Date: 1992 (6) Est Compl Date: 1992

(7) Principal Investigator: Bryan Larsen, MAJ, MC (8) Facility: FAMC

(9) Dept of MED/Gastro. (10) Associate Investigators

(11) Key Words:
helicobacter pylori Jerry Sims, M.D.
salivary antibodies
orasure salivary collection device

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUG b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To determine if salivary antibodies collected
with the orasure collection device is a reliable way to determine the
presence or absence of helicobacter pylori.

(16) Technical Approach: 5cc of blood is obtained via venipuncture,
spun with the serum frozen. Saliva obtained using the orasure salivary
collection device and stored for testing of antibodies. Biopsies
obtained from the stomach for analysis.

(17) Progress: Are actively involved in enrolling patients. Waiting
on schedule progress.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/141 (3) Status: Ongoing

(4) Title: The Relationship of Gout and Hyperuricemia to Hypothyroidism

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Alan Erickson, M.D. (8) Facility: FAMC

(9) Dept of MED/INT.MED. (10) Associate Investigators

(11) Key Words: gout
hypothyroidism Raymond Enzenauer, MD
John Merenich

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUG b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To survey the relationship of gout and hypothyroidism.

(16) Technical Approach: Retrospective and prospective review.

(17) Progress: I have started the prospective study and retrospective chart review.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/142 (3) Status: Ongoing

(4) Title: Clarithromycin in Combination with Omeprazole or Omeprazole as a Single Agent for the Treatment of Patients with Duodenal Ulcers

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Peter McNally, LTC, MC

(8) Facility: FAMC

(9) Dept of MED/Gastro.

(10) Associate Investigators

(11) Key Words:
duodenal ulcer

Dr. Suddeth
Dr. Johns
Dr. Larsen
Dr. Davis
Dr. Root
Dr. Lawrence

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if omeprazole plus clarithromycin is more effective in preventing ulcer recurrence than omeprazole plus placebo.

(16) Technical Approach: Double blind randomized multi-center trial with endoscopic followup for recurrence.

(17) Progress: New protocol, waiting for approval to start.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/143 (3) Status: Ongoing

(4) Title: SWOG 9035 - Randomized Trial of Adjuvant Immunotherapy with an Allogeneic Melanoma Vaccine for Patients with Intermediate Thickness, Node Negative Malignant Melanoma (T3NOMO) Phase III

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Thomas Cosgriff, COL, MC (8) Facility: FAMC

(9) Dept of MED/Hem/Onc (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Sep b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the SWOG group protocol in study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Open for patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/144 (3) Status: Ongoing

(4) Title: Double-Dummy, Double-Blind, Randomized, Single-Center Study on the Effect of Hormone Replacement Therapy on Blood Pressure

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
William Newman, CPT, MC

(8) Facility: FAMC

(9) Dept of MED/Endocrine

(10) Associate Investigators

(11) Key Words:

hormone replacement

b l o o d p r e s s u r e

John Merenich, MAJ, MC

Rhonda Wagner, CPT, AN

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine estrogen replacement therapy effects on blood pressure in post menopausal women.

(16) Technical Approach: This is a 6-month study of 100 women assigned to either Premarin 0.625mg/day, placebo shoulder patch; or Estraderm 0.05mg patch, placebo pill/day. Blood, urine and blood pressure will be monitored.

(17) Progress: New study just approved, awaiting arrival of placebo patches.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/145A (3) Status: Ongoing

(4) Title: The Effects of Methotrexate on Mouse (Mus musculus)
Osteoblasts and Osteoclasts in Culture

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Kimberly May, CPT, USAF

(8) Facility: FAMC

(9) Dept of MED/

(10) Associate Investigators

(11) Key Words:
methotrexate
osteopenia
osteoblasts

Don Mercill, CPS
Sterling West, COL, MC
Michael T. McDermott, LTC, MC

(12) Accumulative MEDCASE:*
*Refer to Unit Summary Sheet of this Report.

(13) Est Accum OMA Cost:*

(14) a. Date, Latest IRC Review: AUG b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 7 adult mice/63 newborns
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: The objective of this study is to determine the
effect of methotrexate (MTX) on mouse osteoblasts (OB) and osteoclasts
(OC) grown in culture.

(16) Technical Approach: Have completed initial part of study;
successfully separated osteoblasts and osteoclasts.

(17) Progress: Have ordered experimental groups of animals. Will have
initial results in three weeks.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/203 (3) Status: Completed

(4) Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Disorders Marked by Altered Patterns of Peripheral Blood Flow

(5) Start Date: (6) Est Compl Date: 6/92

(7) Principal Investigator: Richard A. Sherman, MAJ, MS (8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics (10) Associate Investigators

(11) Key Words: thermography/pain

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 59
d. Total Number of Subjects Enrolled to Date: 214
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area for patients with orthopedic related pain disorders.

(16) Technical Approach: We will make thermographic recordings of groups of ten subjects having one of the following conditions each time they come to Orthopedic Clinic from the initial diagnostic appointment through post-resolution follow-up: Frostbite, Charcot Joints, Carpal Tunnel Syndrome, Fibrositis, Sympathetic Dystrophy and Peripheral Neuropathy, Pre-amputation preparation, and Prediction of Bed Sore Formation. The clinical evaluations will not be related to the thermographic evaluations until the subject has completed participation in the study.

(17) Progress: This study has been superseded by 89/210 which funds the above work.

Presentations: Thermography and Carpal Tunnel Syndrome. Presented to the Barnard Series at the UCHSC, 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 87/204 (3) **Status:** Ongoing

(4) **Title:** Mechanism Based Treatments of Phantom Limb Pain

(5) **Start Date:** 1987

(6) **Est Compl Date:** 1992

(7) **Principal Investigator:**
Richard A. Sherman, LTC, MS

(8) **Facility:** FAMC

(9) **Dept/Svc:** SURG/Orthopedics

(10) **Associate Investigators**

(11) **Key Words:**

phantom limb pain
treatments

Timothy Young, MD, Augusta,
VAMC
Robert Rodinelli, MD,
Denver, VAMC

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report.

(14) a. **Date, Latest IRC Review:** APRIL

b. **Review Results:**

c. **Number of Subjects Enrolled During Reporting Period:** 13

d. **Total Number of Subjects Enrolled to Date:** 96

e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) **Study Objective:** To demonstrate the effectiveness of treatments for burning phantom limb pain.

(16) **Technical Approach:** We will treat four groups of ten amputees each with the same six interventions. The amputees will be grouped by the description of their phantom pain. We will work with those describing their phantom pain as (1) only burning, (2) only cramping, (3) mixed cramping and burning, and (4) shooting / stabbing / shocking. Before treatment begins, there will be a three week baseline in which each amputee will be interviewed and stump muscle tension and heat outflow patterns will be recorded. Each amputee will receive each treatment for one month unless side effects force withdrawal. Treatment months will alternate with three week "washout" periods to permit phantom pain to return to baseline. The treatments will be: (1) topical application of nitroglycerine for mainly venous-side vasodilatative effects, (2) trental to reduce blood viscosity so more blood can reach tissues in the stump having compromised vascular beds, (3) Nifedipine as a Calcium channel blocker for its known peripheral vasodilatative effects, (4) Cyclobenzaprine for its ability to reduce spasms of local origin without interfering with muscle function, (5) muscle tension recognition and relaxation training for its proven ability to reduce microspasms and

tension related to intensification of phantom pain, and (6) body surface temperature recognition and control training for its ability to help people control vasodilation of peripheral vessels while under stress. Subjects will be recorded the same way they were during the baseline at each session to permit objective verification of physiological changes. They will come to the clinic every other week during treatments. At the end of the last treatment, there will be another three week baseline. Following the final baseline, the treatment which proved most effective, if any, will be continued for one year. Subjects will be recorded at monthly intervals. If no treatments are effective, subjects will still be followed for one year but will be recorded at six and twelve months.

(17) Progress: Virtually all patients have burning or cramping phantom pain were cured or helped substantially to the point where no more medication is required. Patients with shocking pain were two exceptions, were either helped marginally or not at all. One of the exceptions found a local herbal medicine that stops the pain which we are investigation with the pharmacy's help. The other learned to avoid permitting the pain to begin by controlling limb temperature.

Publications:

Sherman R, Ernst J, Barja R, Bruno G: Phantom pain: A lesson in the necessity for carrying out careful clinical research in chronic pain problems. Rehabilitation Research and Development, 25(2): vii-x, 1988. (Editorial)

Sherman R, Barja R: Treatment of post-amputation and phantom limb pain. In (K. Foley and R. Payne, eds.) Current therapy of pain. B.C. Decker, Publisher, Ontario, 1988. (Chapter)

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 13(1):55, 1988. (Abstract)

Sherman R, Arena JG, Bruno GM, Smith JD: Precursor relationships between stress, physical activity, meteorological factors, and phantom limb pain: Results of six months of pain logs. Proceedings of the Joint meeting of the Canadian and American Pain Societies, Toronto Canada, November, 1988 (Abstract).

Sherman R: Phantom limb and stump pain. chapter in (R. Portenoy, ed) Neurologic Clinics of North America. W.B. Saunders Co., Publisher, 1989, (Chapter).

Sherman R, Sherman C, Grana A: Occurrence of acture muscle contractions in the residual limbs of amputees preceding acute episodes of phantom limb pain. Biofeedback and Self-Regulations, 1989 (Abstract).

Arena J, Sherman R, Bruno G: The relationship between humidity level, temperature, and phantom limb pain: Preliminary Analysis. Proceedings of the annual meeting of the Association for Applied Psychophysiology, 1989 (Abstract).

Presentations:

Sherman R: Mechanisms of phantom pain: new findings: Presented: Proceedings of the 21 Annual meeting of the Association for Applied Psychophysiology, Washington, D.C., 1990.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 87/206 (3) Status: Completed
-
- (4) Title: Evaluation of Psychophysiological Ways to Assess Chronic Low Back Pain
-
- (5) Start Date: 1987 (6) Est Compl Date:
-
- (7) Principal Investigator: Richard A. Sherman, MAJ, MS
John G. Arena, Ph.D. (8) Facility: FAMC
Augusta, VAMC
-
- (9) Dept/Svc: Clin. Invstgn. (10) Associate Investigators
Jeffrey Ginther, MAJ, MC
Timothy Young, MD, Augusta, VAMC
-
- (11) Key Words: low back pain
thermography
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: JULY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 168
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None
-
- (15) Study Objective: To test the effectiveness of paraspinal surface EMG, the MMPI, videothermography, physical examination, and standard diagnostic procedures for ascertaining objective data concerning the patient's actual low back pain intensity and underlying physical problems.
-
- (16) Technical Approach: We completed process of performing paraspinal surface EMG and videothermographic recordings of at least 360 subjects with low back pain of six diagnostic categories and who hurt most while in one of six different positions (6 x 6 cell design with ten subjects in a group). Each subject is being recorded four times: Twice while their pain intensity is the same and twice while it varies up or down from the two similar recordings. Thus, each subject is recorded at between two and three pain intensities. This provides data on change with time while pain is constant. All of these subjects are given a modified version of the MMPI designed to differentiate between psychological factors and changes in responses due to presence or absence of low back pain. Each subject is also given a complete orthopedic physical examination and any standard diagnostic procedures not already well documented is done.
-
- (17) Progress: The study has been superseded by 89/207 which funds the above work.

Publications:

Arena J, Sherman R. Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in different positions. Pain, 37:57-65, 1989.

Arena J, Sherman R. Bruno G & Young T: Electromyographic recordings of five types of low back pain subjects and non-pain controls in six different positions. Pain, 1990.

Arena J, Sherman R, Bruno G: Professionals and low back pain patients expectations of differences in response patterns on the MMPI as a function of presence or absence of chronic pain. Biofeedback and Self-Regulation, 1989.

Arena J. Sherman R, Bruno G: Reliability of multiple surface electromyographic recordings of the paraspinal muscles among subjects with and without low back pain. Int. J. Psychophysiology, 1989.

Sherman R, Arena J, Bruno: Electromyographic recordings of low back pain subjects in different positions during low and high pain levels. Biofeedback and Self-Regulation, 1989.

Arena J, Sherman R, Bruno G, Young T: Temporal stability of paraspinal electromyographic recordings in low back pain and non-pain subjects. Int. J. of Psychophysiology, 9:32-37, 1990.

Presentations:

Arena J, Sherman R, Bruno G, Young T: Reliability of paraspinal electromyographic recordings in low pack pain and non-pain subjects. Presented: Am. Psychological Assoc., 1988.

Sherman R, Arena J, Bruno G, Young T: Electromyographic recordings of low back pain subjects in different positions vs. results of standard diagnosis. Presented: Am. Psychological Assoc, 1988.

Sherman R, Arena J, Bruno G, Young T: A comparison of surface EMG and thermographic evaluations of five diagnostic categories of low back pain subjects. Presented: Proceedings of the American Pain Society's 1989 annual meeting, Phoenix, AZ October 1989.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/207 (3) Status: Ongoing

(4) Title: Determination of Mechanisms of Phantom Limb Pain:
Phase 2

(5) Start Date: 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Richard A. Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators

(11) Key Words:
phantom limb pain

Jeffrey Ginther, MAJ, MC
JD Griffin, RN

mechanisms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 16
d. Total Number of Subjects Enrolled to Date: 40
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To use MRI, nerve recording, and other techniques to monitor veteran and active duty amputees who report shocking, shooting, and stabbing descriptors of phantom limb pain while they are experiencing various intensities of pain in order to ascertain the physiological changes which are related to changes in pain intensity.

(16) Technical Approach: We will carry out the pilot for a full proposal in which we would record groups of twenty active duty or veteran amputees four times. In the pilot, only two amputees from each group will participate. Two of the recordings will be at one particular pain intensity while the other two will be at two different intensities. This will permit factoring changes due to time from those due to changes in pain intensity. Each subject will be recorded at about weekly intervals but the exact timing will have to depend on when their pain intensity changes. The groups will consist of two amputees with (1) only stabbing phantom pain, (2) only shooting phantom pain, (3) only shocking phantom pain, (4) a combination of all three (which is common), and (5) no phantom pain. The fifth group of amputees without phantom pain is necessary

to further evaluate changes which occur in the normal stump over time so we can differentiate them from abnormal changes. We know from our experience in Phase I of this study that twenty is the minimum number of amputees we can have in a group due to normal physiological variability and in variability in reporting pain intensity. However, two per group will give us an idea of whether the following techniques are likely to show any differences at all. We propose to use MRI to record overall stump anatomy, plethysmography to record swelling and internal stump pressure, and signals from the neuroma to record responses to mechanical and other stimuli. Because of its invasive nature, we will carry out only one nerve signal study from the stump. For subjects who report phantom pain, we will perform the test on a day when they report the maximum phantom pain they usually experience. We will compare the results of this recording with those from pain free amputees. Due to its cost, we will do MRI recordings of only one subject per pilot group. Two MRI's will be done for each pilot subject. One will be while the subject is as pain free as they get and the other will be while they are experiencing the most pain they generally expect.

(17) Progress: Twenty amputees experiencing numerous acute episodes of cramping phantom pain had the surface muscle tension in their residual limbs recorded. They pressed a button during episodes of phantom pain. Temporal relationships between initiation of episodes and spasms in the limb were established. Spasms precede start of pain by more than reaction time so causes the phantom pain.

Publications:

Sherman R, Sherman C, Grana A: Occurrence of acute muscle contractions in the residual limbs of amputees preceeding acute episodes of phantom limb pain. Biofeedback & Self-Regulation 14(2):169, 1989.

Sherman R, Bruno G: Concurrent variation of burning phantom limb and stump pain with near surface blood flow in the stump. Orthopedics, 10:1395-1402, 1987.

Sherman R, Sherman C, Bruno G: Psychological factors influencing chronic phantom limb pain: An analysis of the literature. Pain, 28:285-295, 1987.

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Biofeedback and Self-Regulation, 1988, (Abstract).

Presentations:

Arena J, Sherman R, Bruno G, Smith J: The relationship between situational stress and phantom limb pain: Preliminary analysis. Presented at the 19th Annual meeting of the Society for Applied Psychophysiology in Colorado Springs, CO, March 1988.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/202 (3) Status: Ongoing

(4) Title: A Comparison of Clinical Features of Ulnar Nerve Compression at the Elbow Before and After Medial Epicondylectomy

(5) Start Date: 1989

(6) Est Compl Date: 1990

(7) Principal Investigator:
Dr. Deffer, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: SUR/Orthopedics

(10) Associate Investigators
James C. Johns, MAJ, MC
Douglas Hemmler, CPT, MC

(11) Key Words:
nerve compression
conduction velocity

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MARCH Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 21
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Assess results of medial epicondylectomy in the treatment of cubital tunnel syndrome.

(16) Technical Approach: Comparison of preoperative and postoperative and electrical parameters.

(17) Progress: Approximately 21 patients have undergone the procedure of medial epicondylectomy. Clinical impression is that operation is working well. No adverse reactions recorded. Data continues to be collected. FY 92, the project will be started up in the near future. There has been a large turnover in investigators. This has raised some problems with continuity for the project.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 88/203 (3) Status: Terminated

(4) Title: Evaluation of Current Nasal Surgical Techniques Used to Improve Nasal Obstruction (Subjective and Objective) Utilizing Anterior Rhinometric Techniques

(5) Start Date: 1991

(6) Est Compl Date: 1993

**(7) Principal Investigator:
Michael L. Lepore, COL, MC**

(8) Facility: FAMC

(9) Dept/Svc: SUR/Otolyn/Hd&NkSur. (10) Associate Investigators

**(11) Key Words:
rhinomanometry
nasal obstruction
nasal surgery**

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: MARCH b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: (a) to utilize anterior rhinometric principles in the pre-op assessment of patients prior to nasal surgery, (b) to utilize anterior rhinometric principles in the post-op evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery (opened or closed), and (c) to determine, utilizing anterior rhinomanometric techniques, if the unobstructive nasal cavity after nasal surgery (opened or closed) is significantly altered at the expense of correcting the pre-op obstructive side, and is this subjectively noted by the patient to the point of causing secondary obstructive symptoms, of any degree on the unobstructive side which will be objectively measured.

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(16) Technical Approach: Measurements of nasal airflow utilizing anterior rhinomanometry will be performed before surgery and after surgery at definite periods. Correlation will be made between the various surgical procedures and the measured test results to note if any significant alterations on the unobstructed side have resulted from the surgical procedures.

(17) Progress: This protocol was not started by the Principal Investigator due to multiple administrative problems and inability to set aside the appropriate research time because of lack of staff. The Principal Investigator has retired from active duty, and there are no associate investigators.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/213 (3) Status: Ongoing

(4) Title: Investigational Plan for the Clinical Study of Silicone Intraocular Lenses Sponsored by Allergan Medical Optics

(5) Start Date: 1988

(6) Est Compl Date:

(7) Principal Investigator:
Floyd M. Cornell, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: SURG/Ophthalmology

(10) Associate Investigators:
Robert W. Enzenauer, LTC, MC
Thomas A. Gardner, MAJ, MC
Monte S. Dirks, MAJ, MC
Eric A. Sieck, MAJ, MC

(11) Key Words:
silicone IOL

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to establish the safety and efficacy of the silicone intraocular lens according to FDA regulations.

(16) Technical Approach: The technical approach is the standard surgical method of cataract extraction and lens implantation to treat visually disabling cataracts.

(17) Progress: Two patients have been enrolled to date at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol WU#: 88/215 (3) Status: Ongoing

(4) Title: Environmental/Temporal Relationships Between Headache and Muscle Tension

(5) Start Date: 1988

(6) Est Compl Date: 1994

(7) Principal Investigator:
Richard A. Sherman, LTC, MS

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators
Cecile Evans, BA COL, MC
Carson Henderson, MSW, Psy.D.
Crystal Sherman, MS
Ellynore Cucinell, COL, MC

(11) Key Words:
headache
muscle tension
environmental recording

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 12
d. Total Number of Subjects Enrolled to Date: 32
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e". None

(15) Study Objective: To determine relationships between motion, muscle tension in the frontal and trapezius muscles, and onset and intensity of headaches among subjects recorded in their normal environments.

(16) Technical Approach: Subjects wear a small EMG and motion recorder during all working hours for one week. They keep an hourly log of types and activity and pain intensity while wearing the recorder.

(17) Progress: Data from 5 males and 5 females (ages 22-67) having tension (5), migraine (3), or mixed (2) headaches participating in the study were analyzed. In each case, the wearable device recorded two channels of EMG from the left and right trapezius muscles, movement, and button presses indicating pain intensity. Subjects wore it all day in their normal environments for three to five days. In two subjects (one tension headache and one migraine), trapezius EMG increased before pain increased. In a third subject (tension headache), EMG was elevated during high pain. In a fourth subject (mixed headache), EMG was lower during pain free recordings than during headaches. In a fifth subject (tension headache), EMG decreased after pain increased. There was no relationship between EMG and pain intensity in the remaining subjects (two tension headaches, two migraine headaches, and one mixed). Thus,

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there may be a small sub-set of people who do, in fact, have muscle tension components of their headaches. This is the first time evidence has actually been recorded to support this well accepted but theoretical relationship. All previous, in-laboratory, studies have failed to find any support for the relationship.

Publications: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity. Biofeedback and Self-Regulation, in press, 1992.

Presentations: Sherman RA, Evans CB, Henderson CY, Sherman CJ, Griffin V, and Arena JG: Continuous environmental recordings of relationships between trapezius EMG, movement, activity, and headache pain intensity Presented Annual Meeting of the Association for Applied Psychophysiology, Colorado Springs, 1992.

FAMC A.P.R. (RCS MED 300) Detail Summy Sheet ((HSCR 40-23 as amended)

(1) Date: 3 Mar 92 (2) Protocol #: 89/203 (3) Status: Ongoing

**(4) Title: Rates of Occurrence of Simultaneous and Independent
Low Back Pain and Headache Among Patients with and
without Chronic Pain**

(5) Start Date: 1989 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard A. Sherman, LTC, MS (8) Facility: FAMC

**(9) Dept/Svc: SURG/Orthopedics (10) Associate Investigators:
John G. Arena, Ph.D.
Jeffrey R. Ginther, MAJ, MC
Melissa Damiano, M.S.**

**(11) Key Words:
low back pain
tension headache
incidence**

**(11) Latest IRC Review: MARCH Review Results: Ongoing
Number of Subjects Enrolled During Reporting Period: 15
Total Number of Subjects Enrolled to Date: 80**

**(12) Study Objective: To determine the temporal relationships between
the above pain problems among subjects with and without chronic pain.**

**(13) Technical Approach: Survey deers eligible people with and without
pain while they are waiting for appointment at FAMC.**

**(14) Progress: No results yet as surveys are still being distributed.
Study has been slowed due to lack of staff.**

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/207 (3) Status: Ongoing

(4) Title: Etiology and Progression of Acute Muscle Tension Related Low Back Pain Occurring During Sustained Activity Including Combat Training Exercises

(5) Start Date: Oct 1989

(6) Est Compl Date: Sep 1992

(7) Principal Investigator:
Richard A. Sherman, LTC, MS

(8) Facility: FAMC
& Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: SURG/Orthopedics

(10) Associate Investigators:
David Hahn, LTC, MC
Jeffrey R. Ginther, MAJ, MC
John G. Arena, Ph.D.
(VA, Augusta, GA)

(11) Key Words:
low back pain
EMG

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Ongoing c. Number of Subjects Enrolled During Reporting Period: 18
d. Total Number of Subjects Enrolled to Date: 80
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Determine the etiology and progression of acute muscle tension related low back pain occurring during sustained activity including combat training exercises.

(16) Technical Approach: Use ambulatory recorders to make second by second records of bilateral surface paraspinal EMG and back movement as well as hourly back pain and fatigue rating entries for 20 hours per day while subjects function in their normal environment.

(17) Progress: During the first seven months the project has been in progress the staff has been trained, the equipment has been tested, the test-retest reliability and confidence limits of the system have been established, and the first 62 subjects have completed participation. Of 34 participants seven had no histories or current reports of low back

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pain and were normal upon examination; 23 were diagnosed as having intermittent back pain due to muscle tension, medical problems, 3 were diagnosed as having intermittent low back pain due to disk-nerve entrapment problems, and one had continuous pain due to arthritis. The most outstanding result was that the recordings look very different for subjects with different etiologies of low back pain. Visual inspection alone was sufficient to differentiate controls from people with back pain due to muscle spas. Although we had only 4 cases of people with back pain due to disk or arthritic problems, their recordings also looked very different from those of people with muscle spasms. Among people with muscle spasm related back pain, the muscle tension level was loosely related to activity. Muscle tension began increasing between somewhat less than one minute to forty-five minutes before pain increased. Decreases in tension were followed by decreases in pain about the same duration as later. The magnitude of muscle tension and pain changes tended to be similar. There was little relationship between change in type of activity and changes in pain. The patients with disk problems and the patients with arthritis showed a very distinct relationship between changes in types of activity and changes in pain. There was little or no relationship between changes in muscle tension and changes pain. Several subjects with disk problems did show increases in muscle tension following increases in pain, as one might expect of a reflex reaction or guarding following increased pain.

Publications:

Sherman R, Arena J, Searle J, and Ginther J: Development of an ambulatory recorder for evaluation of muscle tension related low back pain and fatigue in soldiers' normal environments. Military Medicine.

Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/210 (3) Status: Ongoing

(4) Title: Use of Body Surface Heat Patterns for Predicting and Evaluating Acute Lower Extremity Pain Among Soldiers

(5) Start Date: Oct 89 (6) Est Compl Date: Sep 94

(7) Principal Investigator: Richard Sherman, MAJ, MS (8) Facility: FAMC

**(9) Dept/Svc: Orthopedic Svc (10) Associate Investigators: Allyn Woerman, LTC, PT
Ft. Sill, OK
Kent Karstetter, CPT, MC
FAMC**

**(11) Key Words:
thermography
lower extremity pain
surface temperature**

**(12) Accumulative MEDCASE:* (13) Est. Accum OMA Cost: *
*Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: JULY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 154
d. Total Number of Subjects Enrolled to Date: 586
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: To provide immediate, on-site diagnosis of stress fractures in the lower extremities of active duty soldiers using a comparison of high technology videothermography and bone scan with filed viable contact thermography and surface temperature probes.

**(16) Technical Approach: Phase I) Use videothermography and standard physical evaluations to establish baselines for trainees initially entering service at Ft. Sill, OK. Repeat thermograms will be performed on all trainees reporting to the troop medical clinic for treatment of pain in their knees, lower legs, and feet. Thermography will be performed on a matched group of trainees who come in to the clinic for other problems. This will permit differentiation of changes which occur among most trainees from pathological changes.
Phase II) Compare videothermograms, contact thermograms, bone scans and other recordings of 100 trainees and 100 relatively senior soldiers suspected of having stress fractures with similar evaluations of matched controls to establish the efficacy of low technology contact thermography for evaluation of stress fractures.**

(17) Progress: Phase I: Over half of the trainees had asymmetrical patterns during their pro-training baseline. The majority of those developed lower limb pain. Ways to predict which trainees will develop severe lower limb pain will be based on baseline thermograms being developed. Phase II: Contact thermography has been shown to be useless for evaluating lower limb pain in our population because the device can not be pressed against hot areas of the limb.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 89/211 (3) Status: Completed
-
- (4) Title: Randomization Study of Transurethral Resection of the Prostate vs Balloon Dilation of the Prostate for Symptomatic Benign Prostatic Hyperplasia in Men
-
- (5) Start Date: Sep 89 (6) Est Compl Date: Sep 90
-
- (7) Principal Investigator: Craig Donatucci, MAJ, MC
Karl Kreder, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Urology Svc (10) Associate Investigators: Michael Raife, COL, MC
-
- (11) Key Words: transurethral resection of prostate (TURP)
balloon dilation of prostate (BDP)
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 14
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine the effectiveness of balloon dilation of the prostate (BDP) to TURP in moderately symptomatic men over 45 who suffer from benign prostatic hyperplasia (BPH).
-
- (16) Technical Approach: This is a multi-center, two-arm, randomized study to examine the efficacy of BDP in improving symptoms of urinary outlet obstruction and urinary flow in men with symptomatic BPH, and compare and contrast the results with those of men undergoing TURP. Men with urinary outlet obstruction who need TURP and meet the protocol entrance criteria will be randomly assigned to TURP or BDP. After operation the patients will be followed for 1 year to determine improvement in symptoms, urinary flow parameters and post void residual urines. Groups will be compared to determine whether any beneficial effects from BDP have occurred.
-
- (17) Progress: A total of 56 patients were entered, Fitzsimons contributing 25% of the total.

CONTINUATION SHEET FY 92, ANNUAL PROGRESS REPORT PROTOCOL # 89/211

Publications:

Donatucci CF: A randomized, community based study of balloon dilatation of the prostate versus transurethral resection of the prostate. J Urology, 145:391A, 1991.

Donatucci CF: Balloon dilatation of the prostate versus transurethral prostatic resection: A continuing randomized prospective clinical trial. J Urology, 147:307A, 1992.

Presentations:

Donatucci CF: A randomized, community based study of balloon dilatation of the prostate versus transurethral resection of the prostate. 86th Annual Meeting of the American Urological Society, Toronto, Canada, 1991.

Donatucci CF: A randomized comparison of transurethral resection of the prostate versus balloon dilatation of the prostate. Royal Society of Medicine, Vail, CO, 1991.

Donatucci CF: Effectiveness of balloon dilatation of the prostate versus transurethral resection of the prostate, a randomized clinical trial. 39th Annual James C. Kimbrough Urological Symposium, Baltimore, MD, December 1991.

Donatucci CF: Balloon Dilatation of the prostate versus transurethral resection of the prostate: A continuing randomized prospective clinical trial. 87th Annual meeting of the American Urological Association, Washington, DC, May 1992.

The following prize won: 39th Annual James C. Kimbrough Urological Symposium, Resident Competition, Clinical Research, 2nd prize, 2 December 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/200A (3) **Status:** Ongoing

(4) **Title:** Comparison of ACL Graft Fixation Techniques in a Goat Model

(5) **Start Date:** 1990

(6) **Est Compl Date:**

(7) **Principal Investigator:**
Scott D. Gillogly, MAJ, MC

(8) **Facility:** FAMC

(9) **Dept/Svc:** Orthopedic Svc

(10) **Associate Investigators:**
Todd Hockenbury, CPT, MC

(11) **Key Words:**

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** _____ b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** 36
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To determine which of three standard ACL graft fixation techniques provides the best graft fixation in reconstruction of the anterior cruciate ligament utilizing the central one-third of the patellar tendon.

(16) **Technical Approach:** See protocol.

(17) **Progress:** No statistically different strength of different fixation methods after two weeks post-op. May need further goats depending on results of final statistical analysis.

Publications and Presentations: Accepted for presentation for FY 91.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/202 (3) Status: Ongoing

(4) Title: Non-Surgical Treatment of Morton's Neuroma with Injection of Vitamin B-12/Lidocaine/Solumedrol Combination

(5) Start Date: 1990 (6) Est Compl Date: 1992

(7) Principal Investigator: Paul Spezia, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: Orthopedic (10) Associate Investigators:

(11) Key Words:

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: The aim of the first phase is to determine whether the injection produces good enough results with a sufficient percent of the patients to be worth giving as a simple first try prior to offering surgery.

(16) Technical Approach: Our plan is to inject a combination of 0.5cc of lidocaine, 0.5cc solumedrol, and 0.5cc of vitamin B-12 into the interdigital neuroma of all patients in a series of two injections.

(17) Progress: The study injection works as a temporary measure at the 90-day followup. Long-term effects cannot yet be determined as the on-year followup data is pending. No progress this FY year.

Publications and Presentations: Presentation in 1989 at the Barnard Residents's competition.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/203 (3) Status: Ongoing

(4) Title: Synovial and Serum Keratan Sulfate Levels and Their
Correlation with Arthroscopically Determined Articular
Damaged Chronically Deficient Cruciate Ligament Knees

(5) Start Date: 1990

(6) Est Compl Date: 1993

(7) Principal Investigator:
Paul Spezia, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedic

(10) Associate Investigators:
Scott Gillogly

(11) Key Words:
keratan sulfate
arthroscopic cruciate deficient

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if there is a correlation between
keratan sulfate and cruciate deficient knees as determined by
arthroscopy and bone scan.

(16) Technical Approach: No significant data.

(17) Progress: Currently 36 samples harvested. No progress this FY.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/204 (3) Status: Ongoing

(4) Title: A Clinical Comparison of a Hydroxylapatite Coated Versus Porous Coated Total Hip Implant for Use in Arthritic Human Hips

(5) Start Date: 1990

(6) Est Compl Date: Sep 91

(7) Principal Investigator:
Edward Lisecki, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
James Wolfe, CPT, MC

(11) Key Words:
hydroxyapatite

Frederick Coville, COL (RET)

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 10

d. Total Number of Subjects Enrolled to Date: 60

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Compare results of two porous ingrowth hip components to improve amount of ingrowth, thereby, reduce the need for revisions.

(16) Technical Approach: Posterior approach to the hip routine implantation of a porous femoral/acet. component.

(17) Progress: Hip scores on hydroxy apatite hips is consistently higher than the non HA coated hip. HA hip scores run about 8 points higher than non HA for same time period. No adverse reactions to the HA coating have been found.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/206 (3) Status: Ongoing

(4) Title: Pilot Trial of Potentiating Normal Healing of Stress Fractures Using Pulsing Electromagnetic Fields

(5) Start Date: 1990

(6) Est Compl Date: 1994

(7) Principal Investigator:
Kent Karstetter, MAJ, MC

(8) Facility:
Reynolds ACH, Ft. Sill, OK

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
Steven Pals, MAJ, MC
Richard Sherman, LTC, MS
David Teuscher, MAJ, MC
Howard May, LTC, MS

(11) Key Words:
stress fractures
pulsing magnetic fields

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Oct b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 28

d. Total Number of Subjects Enrolled to Date: 28

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate that a full study of pulsing magnetic fields is warranted for treatment of stress fractures.

(16) Technical Approach: Electrical stimulators will be applied to the casts of half of the subjects diagnosed as having stress fractures.

(17) Progress: Eighteen subjects wore a pulsing electromagnetic stimulator in their casts for between 2 and 28 days (mean = 18 days). The results of their treatments did not differ from either ten similar patients who did not receive the stimulation or historical controls. The original protocol required a minimum of 6 weeks on the stimulator. After Desert Shield, new clinical personnel did not keep these patients in casts for that long. The study will be redone with a new P.I. at Fort Sill who is interested in performing the study as designed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/207A (3) Status: Ongoing

(4) Title: Patellar Tendon Healing and Strength Following Patellar Tendon Autograft Harvest in Goats

(5) Start Date: 1990

(6) Est Compl Date:

(7) Principal Investigator:
Steve Pals, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

(10) Associate Investigators:
R. Todd Hockenbury, CPT, MC
Richard Schaefer, CPT, MC
Scott Gillogly, MAJ, MC

(11) Key Words:
autograft
patellar tendon

(12) Accumulative MEDCASE:*

(13) Est. Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine which method of handling the defect from harvesting the central third of the patellar tendon produces stronger, faster healing in the goat.

(16) Technical Approach: See protocol.

(17) Progress: One year study group completed and reported. One year group showed significant decrease in strength in dosed tendon group.

Publications and Presentations: None

Publications and Presentations: J. Investigative Surg.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 90/208A (3) Status: Ongoing
-
- (4) Title: Development of a Tibially Implanted, Percutaneous Limb Prosthetic Holder
-
- (5) Start Date: 1990 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC
-
- (9) Dept/Svc: Orthopedics (10) Associate Investigators:
Philip Deffer, CPT, MC
Ronald L. Jackson, DAC
Edward J. Lisecki, MAJ, MC
William Hall, MD
Stephen Cook, PhD
Paul Glick MAJ, DC
Donald Mercill, DAC
Ronald Banks, MAJ, VC
-
- (11) Key Words:
percutaneous implant
prosthetic
amputees
goats
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To test a percutaneous implant in a goat model to evaluate long term (a) infection through the skin-implant interface, (b) strength of the interface, and (c) ability of the goat to walk on the implanted prosthesis.
-
- (16) Technical Approach: Tissue culture will be used to refine methods for evaluating tissue growth into the prosthesis. A goat model will be used to test which combination of coatings and materials give the best skin adhesion with the least infection and formation of fistulas. The optimal combination will be used to produce a percutaneously implanted prosthetic which will be implanted into several goats to test the above objective.
-
- (17) Progress: Sufficient progress has been made on this protocol that the investigators are ready to begin the next phases of the study. These are very expensive and will require support from outside agencies. Because the proposed work is very complex and potentially risky for the human participants, it is felt that the Institutional Research and LACUC committees should have as much detail as possible available to them when they decide whether the protocol should be forwarded for funding.

Publications & Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/209 (3) Status: Ongoing

(4) Title: Reliability of Psychophysiological Measures Used to Evaluate Pain

(5) Start Date: (6) Est Compl Date: 1995

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: John Arena, Ph.D.

(11) Key Words: chronic pain psychophysiological responses comprehensive assessment Carson Henderson, Psy.D. Richard Calkins, COL, MC Kimford Meador, MD Jeffrey Ginther, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JULY b. Review Results: c. Number of Subjects Enrolled During Reporting Period: d. Total Number of Subjects Enrolled to Date: 11 e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: to evaluate the test/retest reliability of several commonly used psychophysiological measures when used with patients and controls.

(16) Technical Approach: Three groups of chronic low back pain subjects, two groups of tension headache and 75 age-matched controls will be assessed five times. The pain groups will be seen three times when at no or low pain levels and twice when at high pain levels. The assessments will consist of the standard six position measurement of surface EMG patterns, standard psychophysiological evaluations and cold presser test.

(17) Progress: Funding arrived 14 June 1991. The project will begin as soon as the equipment arrives. No progress this FY.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/210 (3) Status: Ongoing

(4) Title: Effectiveness of Treatments for Reflex Sympathetic Dystrophy

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Richard Sherman, LTC, MS (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators:
Douglas Hemler, MAJ, MC
Kent Karstetter, MAJ, MC
Muhammad Shaukat, LTC, MC
Mary Brinkman, MAJ, RPT
CC Evans, BA
Robert Ketchum, COL, MC

(11) Key Words:
reflex sympathetic dystrophy
nerve block
corticosteroids
physical therapy

(12) Accumulative MEDCASE:* (13) Est. Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 8 _____
d. Total Number of Subjects Enrolled to Date: 10 _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the most effective of the standard treatments for reflex sympathetic dystrophy.

(16) Technical Approach: After standard workup and videothermography, subjects will be randomized to one of the three standard treatments--corticosteroids, multiple nerve blocks or vigorous physical therapy. Patients will be followed at 3-mo intervals for one year. If there is no improvement, the patient will be randomized to one of the remaining treatments.

(17) Progress: This study was suspended during Desert Shield and has gradually been reinstituted as sufficient manpower to perform the medical portions of the program becomes available.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/211A (3) Status: Ongoing

(4) Title: Effects of Coumadin and Methotrexate on Bone Ingrowth and Fixation in Hydroxyl Apatite Coated Porous Implants in a Goat

(5) Start Date: 1990 (6) Est Compl Date:

(7) Principal Investigator: James Wolff, CPT, MC (8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho (10) Associate Investigators: Edward Lisecki, MAJ, MC Stephen Cook, Ph.D.

(11) Key Words:
coumadin
methotrexate
bone ingrowth
hydroxyl apatite implants

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 27
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To quantify the biomechanical histological effects of coumadin and methotrexate on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Thirty-six adult goats will be randomized to treatment groups 1-6. Of the coumadin and methotrexate animals, one will be given the medication beginning one month prior to surgery and the other will not receive the medication until the day of surgery. Five transcortical rods will be placed in the femur. Each rod is coated for half its length so each acts as its own comparison control. Specimens will be collected, radiographed and prepared for biomechanical and histological evaluation from 3 to 104 weeks postoperatively.

(17) Progress: MTX has a detrimental effect at a 15 mg dose but not at a 7.5 mg dose. We have encountered problems with fractured femurs. Study is ongoing.

Publications and Presentations: Presented at Barnard Competition, March 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/212A (3) **Status:** Ongoing

(4) **Title:** The Evaluation of Bone Ingrowth in Hydroxyl Apatite and in Non-Hydroxylapatite Porous Implants in a Goat

(5) **Start Date:**

(6) **Est Compl Date:**

(7) **Principal Investigator:**
Edward J. Lisecki, LTC, MC

(8) **Facility:** FAMC

(9) **Dept/Svc:** SURG/Ortho

(10) **Associate Investigators:**

(11) **Key Words:**
bone ingrowth
implants

Stephen Cook, PhD
Jerome Weidel, MD

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** _____ b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** 6
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To quantify the biomechanical and histological effects of hydroxyl apatite on bone growth into porous-coated implants.

(16) **Technical Approach:** The following parameters will be evaluated in a weight loaded goat hip: (a) the interface attachment shear strength and stiffness; (b) rate of development of interfasciary strength and stiffness; (c) the amount, rate and organization of bone ingrowth.

(17) **Progress:** We might need to change the model - we are currently looking at the femurs.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/213 (3) Status: Ongoing

(4) Title: Eaton Trapezial Implant Long-Term Follow-up

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Phillip Deffer, CPT, MC

(8) Facility: FAMC

(9) Dept/Svc: SURG/Ortho

(10) Associate Investigators:
James Johns, MAJ, MC
Frank Scott, MD

(11) Key Words:
eaton trapezialimplant

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 19
d. Total Number of Subjects Enrolled to Date: 19
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To demonstrate through long-term followup that the Eaton trapezial implant provides a strong, stable, mobile and useful thumb without significant complications.

(16) Technical Approach: Retrospective analysis of postoperative records; subjective questionnaire; clinical exam; radiographic evaluation to look for evidence of implant failure, osseous changes or arthritic progression.

(17) Progress: 19 subjects enrolled to date. No results ready yet. Unable to obtain sufficient funds for civilian part of the study. Will recall 19 FAMC patients for additional strength and motion testing and submit paper for presentation/publication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/200 (3) Status: Terminated

**(4) Title: Clinical Evaluation of a Hydrogel Intracorneal Implant
(Kerato-Gel) for the Correction of Aphakia**

(5) Start Date: 1991

(6) Est Compl Date: 1996

**(7) Principal Investigator:
Floyd Cornell, COL, MC**

(8) Facility: FAMC

(9) Dept/Svc: Ophthalmology

**(10) Associate Investigators:
Robert Enzenauer, LTC, MC**

**(11) Key Words:
intracorneal implant
aphakia**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: Oct b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"**

**(15) Study Objective: To improve vision and evaluate a new
intracorneal implant.**

**(16) Technical Approach: Per Allergan Medical Optics protocol as
approved by the FDA for use of this investigational new device.**

**(17) Progress: As yet no patients at Fitzsimons AMC have been
appropriate subjects for this specialized type of lens. The study is
terminated FY 92.**

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/201 (3) Status: Ongoing

**(4) Title: Utilization of Prostheses Among Relatively Healthy
Traumatic Amputees**

(5) Start Date: 1991

(6) Est Compl Date: 1992

**(7) Principal Investigator:
Richard Sherman, LTC, MS**

(8) Facility: FAMC

(9) Dept/Svc: Orthopedics

**(10) Associate Investigators:
Melissa Daminano, MS
Philip Deffer, CPT, MC
Stephen Caminer, BS**

**(11) Key Words:
prosthesis
amputees**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: Jan b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"**

**(15) Study Objective: To determine whether those people who are in
most need of effective prostheses can use them as required.**

**(16) Technical Approach: Two phase study to determine the existence of
sub-groups of otherwise healthy, working age of amputees who may need
different types of prostheses than are currently available. First phase
is to reanalyze data from previous surveys. Second phase is to send
surveys to all 343 of the soldiers discussed above who had traumatic
amputations while on active duty or were otherwise unhurt. This is a
pilot study to determine how the questionnaire needs to be revised and
to determine how many veterans should receive the questionnaire.**

**(17) Progress: None. The VA still has not provided names and
addresses.**

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/202A (3) Status: Ongoing
-
- (4) Title: Ciprofloxacin and Primary Fracture Healing: A Biomechanical and Histological Evaluation in the New Zealand White Rabbit
-
- (5) Start Date: 1991 (6) Est Compl Date: 1991
-
- (7) Principal Investigator: Bert Callahan, CPT, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Surg/Orth (10) Associate Investigators: Edward Lisecki, MAJ, MC
-
- (11) Key Words:
ciprofloxacin
fracture healing
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To evaluate the effect of Ciprofloxacin on primary fracture healing in the rabbit.
-
- (16) Technical Approach: Per protocol approved by LACUC on 19 Feb 91.
-
- (17) Progress: Study is still ongoing. It is too early to form any conclusions. Technique change required procurement of instruments and supplies for plate/screw fixation.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/203A (3) Status: Ongoing
-
- (4) Title: Repair of Femoral Artery by Microvascular Technique in Rabbits and Rats
-
- (5) Start Date: 1991 (6) Est Compl Date: indefinite
-
- (7) Principal Investigator: D.E. Casey Jones, LTC, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Surg/Orth (10) Associate Investigators:
-
- (11) Key Words:
microsurgery
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: This is an ongoing and indefinite study used to maintain proficiency in the microsurgical repair of small vessels, nerves, and tendons. The femoral arteries of rabbits and rats (having a diameter of approximately .7 mm) are ideally suited for this type of study and have been used in past years to maintain proficiency for microvascular technique by the Hand Surgery Service of the Dept. of Surgery.
-
- (16) Technical Approach: Per protocol approved by LACUC on 23 May 91.
-
- (17) Progress: This protocol outlines a well-defined technique for education in, and ongoing skills maintenance for, microsurgical repair of small vessels and nerves. As such, it is an integral part of the hand surgery rotation for the orthopedic residency program at FAMC. With Dr. Jones' assumption of responsibility for the hand surgery service, this protocol will be reactivated in the upcoming months and made a regular part of the hand surgery rotation.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/204A (3) Status: Ongoing
-
- (4) Title: Evaluation of a Gelatin Film Barrier Following Parotidectomy for the Prevention of Frey's Syndrome in the Goat (*Capra hircus*)
-
- (5) Start Date: 1991 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: Vincent Eusterman, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Surg/ENT (10) Associate Investigators: Glen Yoshida, MAJ, MC
-
- (11) Key Words: Frey's syndrome
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 6
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: Twofold: (1) to develop an animal model to produce post-parotidectomy Frey's Syndrome; (2) to objectively document the ability of a gelatin barrier (Gelfilm), to delay the production of Frey's Syndrome following superficial parotidectomy.
-
- (16) Technical Approach: Per protocol approved by LACUC on 18 Jun 91.
-
- (17) Progress: Frey's Syndrome was not produced in the subject animals. Initial pathology did show dissolution of the gel film.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #:91/205 (3) Status: Ongoing

(4) Title: Arrhythmias Following Epinephrine and Cocaine Use During Nasal Surgery

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: William Harpster, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Plastic Surgery (10) Associate Investigators: Jennifer Ladner, CPT, MC

(11) Key Words: arrhythmias David Cheney, MAJ, MC
Berry Morton, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 18
d. Total Number of Subjects Enrolled to Date: 18
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine the incidence of arrhythmias following nasal surgery using the standard regimen of 2% lidocaine with 1:100,000 epinephrine plus 5 ml 4% topical cocaine hydrochloride solution.

(16) Technical Approach: Monitor all patients undergoing nasal surgery, using Holter monitor for 24 hrs before, during and following nasal surgery.

(17) Progress: Interim results presented.

Publications: None.

Presentations: Interim results presented at Association for Military Plastic Surgeons, April 1992.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/206A (3) Status: Ongoing
-
- (4) Title: Use of Goats for Training in Advanced Trauma Life Support
-
- (5) Start Date: 1991 (6) Est Compl Date: Indefinite
-
- (7) Principal Investigator: Phillip Mallory, II, LTC (8) Facility: FAMC
-
- (9) Dept/Svc: Surgery/SICU (10) Associate Investigators: Dick Smith, COL, MC
-
- (11) Key Words:
a d v a n c e d t r a u m a l i f e s u p p o r t
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To provide ealistic training opportunities for physicians in Advanced Trauma Life Support (ATLS) Course.
-
- (16) Technical Approach: Per protocol approved by the LACUC on 12 Aug 91.
-
- (17) Progress: Recently approved, 3 goats were used to train 12 students in September.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/200 (3) Status: Ongoing

(4) Title: Analysis of Wounds by Evaporative Water Loss in Man:
A Pilot Methodology Study

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Henry Jefferson, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators

(11) Key Words:

Sam Cucinell, COL, MC
Richard Gonzalez, Ph.D., USAR
Scott Bennion, LTC, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Develop statistical curve to compare evaporate water loss to wound.

(16) Technical Approach: TWEL device is utilized for this purpose.

(17) Progress: TWEL device is being developed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/201 (3) Status: Ongoing

(4) Title: Effect of Smoking, Alcohol Ingestion, Radiation Therapy
and Beta-Carotene on Langerhans Cells in Human Oral
Mucosa: A Pilot Study

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Richard Kopke, MAJ, MC (8) Facility: FAMC

(9) Dept of SURG/Otolaryngology (10) Associate Investigators
Donald Mercill, DAC
John Peterson, MAJ, MC
Gerald Trammel, COL, MC

(11) Key Words:
langerhans cells
beta carotene
radiation therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 73
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: This study will provide further understanding of
the theory of field cancerization by documenting Langerhans cells (LC)
response to smoking, smoking and alcohol, irradiation and beta-carotene
treatment.

(16) Technical Approach: The density (number) of epithelial LC's will
be quantified histologically using 10 random readings from each of three
microscopic sections. LC number will be expressed as number per mm² of
epithelial surface area of buccal oral mucosa for the following subject
groups: 1) habitual smokers (Grp A) vs Grp C (Control); 2) habitual
smokers and alcohol users (Grp B) vs Grp C; 3) XTR patients (Grp D) vs
Grp C; 4) XRT patients plus beta-carotene (Grp E) vs Grp C; 5) Grp D vs
Grp E; 6) Patients in Grp D and Grp E who continue to smoke and use
alcohol will be subgrouped and compared to Groups A, B, and C as
appropriate.

(17) Progress: 73 of 105 needed patients enrolled. LC counting is
being done; significant differences being found between groups.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/202A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair Utilizing the Rabbit and Rat

(5) Start Date: 1991

(6) Est Compl Date: 1996

(7) Principal Investigator:
Berry Morton, LTC, MC

(8) Facility: FAMC

(9) Dept of SURG/Plastic Surg.

(10) Associate Investigators

(11) Key Words:
training

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Training protocol to attain and maintain proficiency in microvascular surgical repair of small nerves and blood vessels.

(16) Technical Approach: The femoral artery, vein and nerve of the rat is well suited for this type of study. Two animals will be used per week.

(17) Progress: Two people were trained for a total of 75 hours.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/203 (3) Status: Terminated

(4) Title: Cryoprecipitate in the Treatment of Seroma

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Daniel Clark, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Study could not be accomplished without MRDC funding, which was not granted.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/204 (3) Status: Ongoing

(4) Title: Effect of Intravenous Erythromycin on Postoperative Ileus

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Joseph Kolb, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen. Surg.

(10) Associate Investigators

(11) Key Words:

Dr. Hollis

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if erythromycin helps resolve post operative ileus.

(16) Technical Approach: This is a randomized, double-blind study.

(17) Progress: Awaiting randomization of specimens. The project is, in essence, ready to begin.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/205 (3) Status: Terminated

(4) Title: A Multicenter, Double-Blind, Randomized Comparative Study of the Efficacy and Safety of Intravenous Temafloxacin Versus Imipenem-Cilastitin Sodium in the Treatment of Intra-Abdominal Infection

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Jeffry R. Clark, COL, MC (8) Facility: FAMC

(9) Dept of Surgery (10) Associate Investigators

(11) Key Words:
temafloxacin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Abbott Laboratories has voluntarily withdrawn its quinolone antibiotic temafloxacin from worldwide markets as a result of an unexpected profile and incidence of reported serious adverse reactions since the launch of the product.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #:92/206 (3) Status: Ongoing

(4) Title: Intraocular Liquid Silicone for Complicated Retinal Detachments. (IDE)

(5) Start Date: 1992 (6) Est Compl Date: 1995

(7) Principal Investigator: William Waterhouse, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Ophthalm/Surg. (10) Associate Investigators:

(11) Key Words: silicone oil Robert Dragoo, COL, Mc

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: JUNE b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Clinical trial of intraocular liquid silicone for treatment of complicated retinal detachments.

(16) Technical Approach: See protocol.

(17) Progress: 6-month review high risk study. No progress, HSC approved 14 May 1992.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/207 (3) Status: Ongoing

(4) Title: Vivonex Ten Versus Immun-Aid in a SICU Population:
Effects on Restoring Normal Protein Markers

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Henry Jefferson, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen.Surg.

(10) Associate Investigators

(11) Key Words:

Dr. Mallory
Dr. Hammond
Joan Friend

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare two enteral formulas in respect to nutritional aspects.

(16) Technical Approach: Protocol will take place in SICU.

(17) Progress: Will start enrolling patients into protocol as of 1 Oct 92.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/208 (3) Status: Ongoing

(4) Title: Response of Serum Cytokines in Patients Undergoing
Laparoscopic Cholecystectomy to Support the Use of
Laparoscopic Techniques for Other Surgery

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
John Cho, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Gen. Surg.

(10) Associate Investigators

Dallas Homas, CPT, MC

(11) Key Words:

cytokines

cholecystectomy

Jeffrey Clark, COL, MC

Matthew Schofield, CPT, MS

Sharon Hammond, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate that the clinical benefits seen in minimally invasive laparoscopic gallbladder surgery versus open cholecystectomy result from a lack of cytokine release leading to attenuation of the acute phase response..

(16) Technical Approach: Measuring 11-6 the acute phase protein-C-reactive protein- and demonstrating a correlation between and a diminution of cytokine and APP release in laparoscopic versus open cholecystectomy should prove this point.

(17) Progress: None. PI on 6-month TDY.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 92/209 (3) **Status:** Ongoing

(4) **Title:** A Randomized Study of the Stryker OP Device vs Bone Autograft for the Treatment of Tibial Non-Unions

(5) **Start Date:** 1992

(6) **Est Compl Date:** 1995

(7) **Principal Investigator:**
Edward Lisecki, LTC, MC

(8) **Facility:** FAMC

(9) **Dept of** SURG/Orthopedics

(10) **Associate Investigators**
Philip Deffer, Jr., CPT, MC

(11) **Key Words:**
non union BMP
IDE

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report.

(14) a. **Date, Latest IRC Review:** MAR/SEP b. **Review Results:** _____

c. **Number of Subjects Enrolled During Reporting Period:** _____

d. **Total Number of Subjects Enrolled to Date:** _____ 1

e. **Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) **Study Objective:** To increase the rate of healing of tibial non unions.

(16) **Technical Approach:** Non union debridement either use crest graft or OPI.

(17) **Progress:** One patient enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/210A (3) Status: Ongoing

(4) Title: Microsurgical Training in Free Flap Transfer and Vessel and Nerve Repair in Rabbits and Rats

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Glen Yoshida, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/Otolaryn

(10) Associate Investigators

(11) Key Words:

Richard Kopke, MAJ, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Training of Oto-HNS residents, staff in microsurgical techniques for nerve and vessel repair.

(16) Technical Approach: Transection and repair of femoral nerve, artery, vein of the rat/rabbit utilizing microsurgical techniques.

(17) Progress: Continuing protocol, weekly sessions.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/211A (3) Status: Ongoing

(4) Title: The Staffland Rabbit as a Model for Induced Bipolaris Sinusitis

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Richard Kopke, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/Otolaryngology

(10) Associate Investigators

(11) Key Words:
fungal sinusitis
B. polaris species
stauffland rabbit

L. Ziesbe, LTC, MC
C. Sinha, MAJ, MC
R. Harris, LTC, MS
R. Banks, MAJ, VC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: APR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the stauffland rabbit may serve as a model for experimental bipolaris fungal sinusitis.

(16) Technical Approach: Anesthetized animals will have their parinasal sinus ostia occluded surgically, and imourlated with different concentrations of fungal hyphae. The animals will be euthanized and observed for fungal infection.

(17) Progress: The fungal organism has been grown and quantitative methodology developed. The surgical procedure in the rabbit has been worked out on specimens.

Publications and Presentations: None to date.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/212 (3) Status: Ongoing

(4) Title: The Incidence and Association of Carpal Ligamentous Injuries with Distal Radius Fractures

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
John Reiser, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Orthopedics

(10) Associate Investigators
LTC D.E. Casey Jones, MC
MAJ Kevin Rak, MC
MAJ Bernard Borosky, MC

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine the incidence of carpal ligament injury with distal radial and ulnar fractures. Additionally, we will determine the association between the incidence of carpal ligament injury and the classification on severity of distal forearm fractures.

(16) Technical Approach: Data from MRI and radiographic evaluations will be compiled as to severity and classification of the fractures. This data will be analyzed statistically for an association of ligaments injury with distal radial and ulnar fractures, and the incidence with which this association occurs. Carpal ligament injury will be analyzed for association with severity on classification of distal radial and ulnar fractures.

(17) Progress: Eighteen patients have completed MRIs which have been reviewed. Plan, power study of data of 30 cases.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/213 (3) Status: Ongoing

(4) Title: Efficacy of Percutaneous Release of the Trigger
Finger: An Anatomic Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
D.E. Casey Jones, LTC, MC

(9) Dept of SURG/Orthopedics (10) Associate Investigators

(11) Key Words:
CPT Steven Friedel, MD

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To anatomically check the efficacy of the
percutaneous release.

(16) Technical Approach: A percutaneous release will be followed by a
standard open release (to determine if the percutaneous release has
completely divided the A1 pulley).

(17) Progress: 17 releases have been performed using this protocol. We
anticipate doing a power study of our data at 30 cases.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/214 (3) Status: Ongoing

(4) Title: Centocor: HA-1A Efficacy in Septic Shock Trial (CHESSTrial) Centocor Protocol C0041T20 dated 29 May 92.

(5) Start Date: 1992 (6) Est Compl Date: 1993

(7) Principal Investigator: Phillip Mallory, LTC, MC (8) Facility: FAMC

(9) Dept of Surg/General (10) Associate Investigators
Jack L. DePriest, MAJ, MC

(11) Key Words:
septic shock
HA-1A
monoclonal antibody
investigational new drug

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost: *
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine if the HA-1A monoclonal antibody reduces 14-day mortality in patients with gram negative shock.

(16) Technical Approach: Randomized, placebo-controlled, double-blinded, multi-institutional study.

(17) Progress: After the study was approved, the investigators were informed that the military is not allowed to perform placebo trials without the patient's own consent. Family and guardians are unable to give consent. This simply means that doing almost any meaningful critical care research is impossible, as will be evidenced when this study is complete. Any future involvement in collaborative studies will be a waste of time.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/215 (3) Status: Ongoing

(4) Title: Comparison of Three Pneumatic Compression Devices in 300 Total Hip and Knee Replacement Patients.

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Edward Lisecki, LTC, MC (8) Facility: FAMC

(9) Dept of SURG/Orthopedics (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine which three pneumatic compression devices is most effective in preventing DVT.

(16) Technical Approach: Patients will be randomly assigned to one of three pneumatic compression devices following total hip or total knee replacement. Patients will be monitored for clinical signs of DVT. Also, patients will undergo doppler ultrasound if DVT are suspected, or on their 10-14th day post-op.

(17) Progress: Study was recently approved, hope to begin enrolling subjects soon.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/216 (3) Status: Ongoing

(4) Title: Comparison of Three Postoperative Autologous Blood Transfusion Techniques (Haemonetics Cell Saver, AUTOVAC LF System, and Stryker ConstaVac System) in 300 Total Hip and Knee Replacements

(5) Start Date: 1992 (6) Est Compl Date:
1 9 9 4

(7) Principal Investigator: (8) Facility: FAMC
Steven Friedel, CPT, MC

(9) Dept of SURG/Ortho (10) Associate Investigators

(11) Key Words: Edward J. Lisecki, LTC, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare three methods of postoperative autologous blood transfusion. Methods will be compared for; amount of blood recovered/reinfused; amount of blood bank transfusions required; hemolysis of collected blood product, bacterial contamination of collected blood product; febrile reactions; fat embolism syndrome.

(16) Technical Approach: 300 patients will be randomly assigned to one of three methods of postop autologous blood transfusion following total hip or totoal knee replacement.

(17) Progress: Study was just approved, hope to be enrolling subjects soon.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/217 (3) Status: Ongoing

(4) Title: Hybritech Treatment Protocol: Detection of Colorectal Carcinoma Using Hybri-CEAker in Patients with Primary, Recurrent, Metastatic or Occult Disease

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Bradley Bute, MAJ, MC

(8) Facility: FAMC

(9) Dept of SURG/General Surgery

(10) Associate Investigators
Mike McBiles, MAJ, MC

(11) Key Words:
anti CEA monoclonal antibody for
colorectal cancer

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP/MAR b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine efficacy of anti-CEA monoclonal antibody in detecting (recurrent) colorectal carcinomas, as well as safety of IND.

(16) Technical Approach: Indium ¹¹¹- labelled monoclonal antibody studied with state of the art nuclear medicine gamma scanners and compared to operative or other diagnostic findings.

(17) Progress: Pending patient enrollment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/218A (3) Status: Ongoing

(4) Title: Effect of Nicotine on Bone Ingrowth and Fixation in Hydroxyapatite Coated and Uncoated Porous Co-Cr-Mo Alloy Implants in a Goat Model

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Bert C. Callahan, CPT, MC

(8) Facility: FAMC

(9) Dept of SURG/Ortho

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To quantify the biomechanical and histological effects of nicotine on bone ingrowth and fixation strength of porous coated implants.

(16) Technical Approach: Thirty goats will be randomly assigned to type of treatment (7 ng/d, 21 ng/d, or control). Four rods which are hydroxyapatite coated for one-half of their length will be placed into each femur of each goat. Following euthanasia at 3, 6, 12, 26 or 52 weeks, the implants will be removed and tested to determine bony ingrowth and fixation strength.

(17) Progress: Study is still in pilot phase. Investigators are trying to determine the nicotine levels in the goats.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 77/300 (3) Status: Ongoing

(4) Title: Immunologic Disorders in Children and Adults.
I. Correlation of Immune Function in the Immunodeficiency State. II. Correlation of Immune Function of Leukemia and other Childhood Malignancies

(5) Start Date: 1977 (6) Est Compl Date: Open-Ended

(7) Principal Investigator: Michael Lieberman, LTC, MS (8) Facility: FAMC

(9) Dept of Clin Investigation (10) Associate Investigators
Shannon M. Harrison, LTC, MC

(11) Key Words:
immunologic diseases

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: SEP____ b. Review Results: Ongoing____
c. Number of Subjects Enrolled During Reporting Period: 73____
d. Total Number of Subjects Enrolled to Date: 1614____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Existing specialized immunochemical procedures will be consolidated into a registered protocol for use on a consultative basis by the FAMC hospital staff.

(16) Technical Approach: Serum gammopathics evaluated by SPEP, IEP, and rate nephelometry. Lymphocyte phenotyping, DNA analysis, and neutrophil activation potential by flow cytometry. Lymphocyte activation determined by quantitative mitogenesis.

(17) Progress: We continue to provide specialized immunological evaluations and testing with this protocol.

Presentations:

(1) Brown, G.L., and Heggers, J.: Medical Mycology: Assessment of Bacteriologic and Serologic Parameters of Clinically-important Mycoses Normal and Immunologic Comprised Host. Presented: American Medical Technologist Educational Seminars, Denver, CO, July 1979.

(2) Dolan, W., Hill, S., Hasbargen, J., Rickman, W., and Weber, R.: Acquired Hypogammaglobulinemia with Absence of Leu-12 Antigen Following Bilateral Nephrectomy and Renal Transplantation for Goodpasture's Syndrome. Presented: 14th Annual Allergy--Immunology Symposium, Aurora, CO, 21-23 January 1986.

(3) Rickman, W.J., Lima, J.E., and Muehlbauer, S.L.: U.S. Army HTLV-III Testing Program Flow Cytometry Workshop. Presented: 11th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists, San Antonio, TX, 18-20 March 1986.

(4) Rickman, W.J.: Epidemiology, Pathogenesis and Military Implications of HTLV-III Infection. Presented: Health Service Command Annual Pharmacy Conference. Aurora, CO, 5-9 May 1986.

(5) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Lymphocyte Subsets in Human Immunodeficiency Virus Infection: A Prospective Study. Presented: 2nd Annual Symposium of the Rocky Mountain Flow Cytometry Users Group, Albuquerque, New Mexico, 10-11 September 1986.

(6) Rickman, W.J., Harrison, S.M., Lima, J.E., Muehlbauer, S.M., and Schaff, R.: Human Immunodeficiency Virus (HIV) Natural History Study: Abnormal Proliferation of Leu-7 Positive Suppressor T Cells in Asymptomatic Seropositive Patients. Presented: United States Army AIDS Conference, Arlington, VA, 16-18 September 1986.

(7) Stewart, RS, and Hoyt, AJ: Utilization of an Automated Windowless Geiger Chamber Apparatus In Lieu of Liquid Scintillation for Lymphocyte Transformation Assays. Presented: 15th Annual Meeting of the Society of Armed Forces Medical Laboratory Scientists. Baltimore, MD, March 1990.

Publications:

Smolin, M.R., Hasbargen, J., and Rickman, W.J.: Profound Panhypogammaglobulinemia in a Renal Transplant Recipient. Ann. Int. Med.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 82/302 (3) Status: Ongoing

(4) Title: The Evaluation of Recently Introduced, Commercially Available Clinical Microbiology Products for Possible Use in the FAMC Diagnostic Microbiology Laboratory

(5) Start Date: FY 84

(6) Est Compl Date: Ongoing

**(7) Principal Investigator:
Pari L. Morse**

(8) Facility: FAMC

(9) Dept of Clin Investigation

(10) Associate Investigators

**(11) Key Words:
microbiology
microbiological techniques**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: JULY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: To evaluate introduced products which are of interest to the Microbiology Service, Department of Pathology, FAMC, but which cannot adequately be evaluated within the laboratory due to time, personnel, and monetary constraints. This evaluation will include cost effectiveness, ease of use, reproducibility and speed.

(16) Technical Approach: A separate protocol will be designed for each product evaluated.

(17) Progress: Evaluation of a ELISA kit (Ortho) for the measurement of antibody to hepatitis C (formerly non-A, non-B). This kit appears useful for large scale screening but is not specific enough for confirmation of Hepatitis C. Evaluation of a western blot kit (CHIRON-RIBA) for the measurement of antibody to Hepatitis C in sera. This kit

Progress continued - appears to be more specific than the ELISA (ORTHO). We recently evaluated a second generation Western Blot kit (CHIRON-RIBAI) and found it to be more sensitive in detecting antibodies to Hepatitis C in serum than the original RIBA method. Several kits are under consideration including Hepatitis D and a DNA probe for H. influenza.

Evaluation of an ELISA kit (Whittaker), RheumELISA, for the detection of autoantibodies to Sm, RNP, SS-A/Ro, SS-B/La. Patients with a positive ANA screen were tested using this kit. It was found to be too sensitive for clinical use. Several kits are under consideration for evaluation including an ELISA for Helicobacter pylori.

Presentations:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococci by Direct Swab Micronitrus Acid Extraction Technique. Presented: a) Uniformed Services Pediatric Seminar, Norfolk, VA, March 1985; b) 5th Annual Conference on Military Pediatrics Research, Aspen, CO, July 1985;) 14th Aspen Conference on Pediatric Research, Aspen, CO, July 1985.

Publications:

Nelson, S.N., Merenstein, G.B., Pierce, J.R., Arthur, J.D., Engelkirk, P., Morse, P.L.: Rapid Identification of Group B Beta-Hemolytic Streptococcus by Direct Swab Micronitrus Acid Extraction Technique. J. Clin. Microbiol.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/301 (3) Status: Completed

(4) Title: Biology of Cutaneous Lupus: I Skin Lesion Examination

(5) Start Date: 1989

(6) Est Compl Date: 1991

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:

(11) Key Words:
lupus erythematosus
immunofluorescence
icam

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 20

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether systemic lupus erythematosus, discoid lupus erythematosus, and subacute lupus erythematosus can be differentiated by specific auto-antibody binding patterns in the skin using immunofluorescent staining techniques.

(16) Technical Approach: Direct immunofluoresence, immunoperoxidase staining, H&E histology.

(17) Progress: Since the last update no new data has been collected. Two papers have been written. One has been submitted to the Journal of Investigative Dermatology and the other is in the process of revision and addition of new data. No new experiments are anticipated under this protocol in the near future, therefore we request that the protocol be terminated.

Publications: Two papers in progress - 3 abstracts given.

Presentations: Western Regional Meeting of the American Federation of Clinicial Research; National Meeting of the Society of Investigative Dermatology; National Meeting of the American College of Rheumatology. Poster Presentation at the Annual Meeting of the American Society of Dermatopathology.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/302 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: II Characterization of
Autoantigens and Autoantibodies in Lupus

(5) Start Date: 1989

(6) Est Compl Date: 1992

(7) Principal Investigator:
Scott Bennion, LTC, MC

(8) Facility: FAMC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:

(11) Key Words:
neonatal lupus erythematosus
autoantigens
autoantibodies
Ro

Lela Lee, MD, UCHSC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: NA

d. Total Number of Subjects Enrolled to Date: NA

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The major objectives of this project are to characterize the autoantigens and autoantibodies involved in neonatal lupus erythematosus (NLE) and subacute cutaneous lupus erythematosus (SCLE) and to determine if certain characteristics of the autoantigens or autoantibodies can be related to the major clinical findings in these diseases.

(16) Technical Approach: Immunoblotting technique, cloning of Ro, rabbit immunization with Ro to attempt to produce animal model.

(17) Progress: Western blotting has been completed on all sera from neonatal lupus mothers and from patients with subacute cutaneous lupus erythematosus. These results were reported in part in a presentation at the European Society for Dermatologic Research in Copenhagen in June 1991, and confirmed immunodiffusion results reported in a paper submitted for publication, and presently in the process of revision.

CONTINUATION SHEET, FY 92, ANNUAL PROGRESS REPORT Protocol #89/302

Presentation: European Society for Dermatologic Research, Copenhagen, Denmark, June 1991. "Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence".

Abstract: David KM, Bennion SD, DeSpain JD, Golitz LE, Lee LA: Subacute cutaneous lupus erythematosus is distinguishable clinically, histologically, and by immunofluorescence.

Publications: David KM, Bennion SD, DeSpain JD, Golitz LE, Lee LA: The clinical, histologic, and immunofluorescent distinctions between subacute cutaneous lupus erythematosus and discoid lupus erythematosus. Submitted for publication, J Invest Derma., 1991.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/303 (3) Status: Ongoing

(4) Title: Biology of Cutaneous Lupus: III The Study of the Effects of Ultraviolet Light on the Skin of Lupus Erythematosus Patients

(5) Start Date: 1989

(6) Est Compl Date: 1992

(7) Principal Investigator:
Scott Bennion, LTC, MC
Lela Lee, MD

(8) Facility: FAMC
UCHSC

(9) Dept/Svc: Dept Clin Invstgn

(10) Associate Investigators:

(11) Key Words:
ultraviolet light
cutaneous lupus

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: FEB b. Review Results:

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To investigate and better correlate the cutaneous lupus subsets with their respective responses to ultraviolet light to be performed by phototesting patients with systemic lupus erythematosus (SLE), discoid lupus erythematosus (DLE) and subacute cutaneous lupus erythematosus (SCLE) then analyzing tissue and serologic specimens.

(16) Technical Approach: UV exposure followed by immunfluoresenct.

(17) Progress: Since last protocol summary no progress has been made. We continue to encounter the same problems as noted earlier. We have been unable to find a patient to determine UV dosage. We wish to extend the protocol an additional year during which we hope to find a suitable subject; if no subject can be found within the year, we will terminate the protocol. The data collected by such a protocol would be valuable since no previous studies in this area have been done.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/301 (3) Status: Completed

(4) Title: Videx (2', 3'dideoxyinosine, ddI) Open Label Study
Protocol No. 454-999-002 (Bristol-Myers Co)

(5) Start Date: 1990 (6) Est Compl Date: 1991

(7) Principal Investigator: Robert H. Gates, LTC, MC (8) Facility: FAMC

(9) Dept/Svc: DCI (10) Associate Investigators:
Shannon M. Harrison, LTC, MC
William R. Byrne, LTC, MC
Rowland N. Hannon, PA-C

(11) Key Words:
HIV therapy
anti-retroviral therapy
reverse transcriptase inhibitor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period: 1_____
d. Total Number of Subjects Enrolled to Date: 2_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e" Peripheral neuropathy, which developed in one subject, was reported to the sponsor.

(15) Study Objective: Treatment with ddi in patients with severe ARC or AIDS who clinically deteriorate on Zidovudine therapy and cannot participate in NIAID phase II study.

(16) Technical Approach: Study design is an open label salvage treatment using 2', 3' dideoxyinosine (ddi), in patient with advanced HIV disease. These patients are followed in the Infectious Disease Clinic at Fitzsimons Army Medical Center, and treated according to protocol, and in coordination with the sponsor.

(17) Progress: To date, two patients have been treated with ddi on this protocol. One patient, as noted above, had the drug discontinued secondary to peripheral neuropathy. This peripheral neuropathy has improved greatly off drug. The other patient has noted improved energy, appetite, and sense of well-being. This patient remains clinically stable, without obvious adverse side effects. This protocol is being phased out because VIDEX is now approved as a prescription drug.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/300 (3) Status: Ongoing

(4) Title: Prospective Collection and Banking of Lymphocytes and
Clinical Data on HIV Infected Individuals Taking
Antiretroviral Agents

(5) Start Date: 1991

(6) Est Compl Date: 1997

(7) Principal Investigator:
Harris, Richard W., LTC, MS

(8) Facility: FAMC

(9) Dept/Svc: DCI

(10) Associate Investigators:

David Cohn, MD, DH&H

(11) Key Words:
antiretroviral

Chip Schooley, MD, UCHSC
Douglas Mayers, MD, WRAIR

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Aug b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a resource collection of lymphocytes
and clinical information on HIV infected patients who are taking
antiretroviral agents in known amounts and duration on other protocols.

(16) Technical Approach: Update of history and physical parameters
every 12 weeks, collection of 2×10^7 lymphocytes after CD4 helper
enumeration, beta-2 microglobulin and P24 antigen every 12 weeks, chem
18 every 12 weeks, skin testing every 12 weeks (desirable but not
essential).

(17) Progress: None, recently approved study submitted for MRDC
funding.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

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- (1) **Date:** 30 Sep 92 (2) **Protocol #:** 91/301A (3) **Status:** Ongoing
-
- (4) **Title:** Evaluation of Biological Attachment Factors for Skin Graft Acceptance in Athymic Nude (beige/nude/Xid) Mice
-
- (5) **Start Date:** 1991 (6) **Est Compl Date:**
-
- (7) **Principal Investigator:** Donald Mercill, DAC (8) **Facility:** FAMC
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- (9) **Dept/Svc:** CI/Cell Phys (10) **Associate Investigators:** Ronald Jackson, CPT, MS
Scott Bennion, LTC, MC
-
- (11) **Key Words:** skin graft
-
- (12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report
-
- (14) a. **Date, Latest IRC Review:** _____ b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** _____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**
-
- (15) **Study Objective:** The objective of this study is to investigate whether biological attachment factors can be used beneficially in vivo, particularly in skin grafting techniques.
-
- (16) **Technical Approach:** Per protocol approved by LACUC on 18 Jul 91.
-
- (17) **Progress:** As of 25 June 92 all mice have harvested. The remaining 20 will be harvested the last week of July. At that time graft will be sectioned for H&E and immunohistochemical staining.
-
- Publications and Presentations:** None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/302A (3) Status: Ongoing

(4) Title: Training for Department of Clinical Investigation and Veterinary Services Personnel in Medical, Surgical, and Emergency Care and Treatment, and Laboratory, Pathology, and Radiologic Procedures for Various Laboratory Animal Species

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Ron Banks, MAJ, VC (8) Facility: FAMC

(9) Dept/Svc: CI/Animal Res (10) Associate Investigators: Marta Acha, CPT, VC

(11) Key Words: training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide training in routine and emergency medical, surgical, laboratory, pathology and radiology procedures for personnel of the Department of Clinical Investigation and Veterinary Services, using government-owned animals.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jul 91.

(17) Progress: Continue to use as mechanism for personnel training.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/300 (3) Status: Ongoing

(4) Title: Studies on Mycobacterium avium. I. Determination of the Minimum Inhibitory Concentration (MIC) and the Minimum Bactericidal Concentration (MBC) of Various Anti-Mycobacterial Agents and Synergistic Effects with Combinations of Agents

(5) Start Date: 1992

(6) Est Compl Date: 1994

(7) Principal Investigator:
Michael Lieberman, LTC, MS

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

(11) Key Words:

antibiotic synergy
mycobacterium avium

LTC Richard Harris, MS
Donald Paine, DAC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: (1) Determine values for the MICs and MBCs for each antibiotic with each of the study strains of *M. avium*; (2) calculate the MIC 90 and MBC 90 values for each antibiotic (the MIC or MBC for at least 90% of the strains, respectively); (3) calculate an index of synergy for various combinations of anti-mycobacterial agents by determining MIC and MBC values for each agent in the presence of fractional MIC or MBC concentrations of the other agents and in the absence of other agents.

(16) Technical Approach: Laboratory benchwork as described in technical detail in the protocol methodologies.

(17) Progress: MIC's or 7 antimycobacterial agents have been determined for 3 strains of *M. avium* and the synergistic potential of various combinations of two of these antibiotics determined.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 92/301 (3) Status: Ongoing
-
- (4) Title: Molecular Epidemiological Studies on Bacterial Isolates
from Patients on Intensive Care Units and Other Wards
at FAMC
-
- (5) Start Date: 1992 (6) Est Compl Date: 1993
-
- (7) Principal Investigator: Richard Harris, LTC, MS (8) Facility: FAMC
-
- (9) Dept of DCI (10) Associate Investigators
-
- (11) Key Words: Pari Morse, DAC
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".
-
- (15) Study Objective: Determine feasibility of epidemiological typing
of bacterial isolates by plasmid analysis.
-
- (16) Technical Approach: A minilysate procedure was used for rapid
extraction of several groups of clinical isolates. Whole plasmid
extracts and restriction enzyme digests were compared.
-
- (17) Progress: The technique was found to be useful in strain
comparison of several species of clinical isolates. Comparisons of
clusters of infections are now being performed.
- Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/302 (3) Status: Terminated

(4) Title: Molecular Epidemiology Studies of Mycobacterium avium
Isolates from HIV-Infected Patients

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Richard Harris, LTC, MS

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: Not able to allocate personnel and resources to carry
out protocol.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/303A (3) Status: Ongoing

(4) Title: The Determination of Hemoglobin (Hb) Coefficients of
Sheep and Goat Whole Blood Utilizing the IL 482
Co-Oximeter

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Ronald Jackson, Ph.D.

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

(11) Key Words:
hemoglobin
methemoglobin
goat
sheep

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To experimentally determine the hemoglobin coefficients of sheep and goat whole blood utilizing an instrumentation laboratory model 482 xo-oximeter.

(16) Technical Approach: Whole blood from 10 goats and 10 sheep will undergo a series of chemical reactions and equilibration with known gas concentrations to isolate the different fractions of hemoglobin within the blood. Using an IL 482 co-oximeter, absorption coefficients will be determined and the levels of hemoglobin fractions will be calculated and stored in the 482's microprocessor memory. All results will be validated by accepted laboratory standards.

(17) Progress: All supplies and precision gases have been ordered for this study. The carbon monoxide, however, has not arrived, therefore, the study has not commenced.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/304A (3) Status: Ongoing

(4) Title: Evaluation of Serotonin (5-hydroxytryptamine), Bleeding Times, and Blood Platelets in Athymic Nude and Normal Mice

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Don Mercill, GS11

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

(11) Key Words:
serotonin
athymic nude mice
bleeding times

Ronald Jackson, Ph.D.
Scott Bennion COL, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study will determine blood levels of serotonin (5-hydroxytryptamine, 5HT), platelet counts, and bleeding times of three strains of athymic nude mice and compare the findings with the same parameters measured with other strains.

(16) Technical Approach: Twelve mice from three strains and six mice each from two different strains (total 48 mice) will be anesthetized and assays for bleeding times, serotonin levels, and platelet counts performed. Six mice from each group will be injected with serotonin twenty minutes prior to the study procedures.

(17) Progress: Protocol has not been started, due in part to loss of over 40% of the staff, and the additional three new protocols which directly support GME. These involve training of laboratory procedures to investigators as well as providing research support for these new protocols.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/305A (3) Status: Terminated

(4) Title: Effectiveness of Ketoprofen in Goats (Capra hircus)

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
Ronald Banks, MAJ, VC

(8) Facility: FAMC

(9) Dept of DCI

(10) Associate Investigators

(11) Key Words:
analgesia
goats
ketoprofen

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To determine whether ketoprofen is an effective analgesic for goat orthopedic injuries.

(16) Technical Approach: (1) cause acute inflammatory arthritis; (2) provide ketoprofen in a variety of doses and delivery routes; (3) monitor and measure the effectiveness of the medication.

(17) Progress: Study discontinued after 4 animals as data indicated there to be negligible beneficial effect from ketoprofen in goats.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/306A (3) Status: Ongoing

(4) Title: Evaluation of the Blacktailed Prairie Dog Cynomys ludovicianus as a Model for Hepadnavirus Replication

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Kenneth E. Sherman, MAJ, MC (8) Facility: FAMC

(9) Dept of DCI (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To evaluate the black-tailed prairie dog for a potential model for replication of hepatitis B-like viruses.

(16) Technical Approach: (a) Development of laboratory colony of prairie dogs followed by infection with four hepadnavirus agents (b) Field collection and evaluation of wild prairie dogs.

(17) Progress: (a) Colony of prairie dogs established and husbandry techniques developed (b) 13 wild prairie dogs evaluated. Histological evidence of hepatitis found in 3.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/351 (3) Status: Ongoing

(4) Title: Section A: Master Protocol for Phase II Drug Studies in the
Treatment of Advanced Recurrent Pelvic Malignancies
GOG 26 A

(5) Start Date: 4/14/86

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, not a treatment protocol.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/352 (3) Status: Ongoing

(4) Title: Section C: A Phase II Trial of CIS-Platinum
GOG 26 C

(5) Start Date: 4/27/77 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 3
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients; one partial remission. No adverse reactions.

Publications and Presentations: Multiple by GOG, none by FAMC.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/359 (3) Status: Ongoing

(4) Title: Section S: A Phase II Trial of VM26
GOG 26

(5) Start Date: 7/9/84 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Four patients, three progressive disease, 1 stable. No adverse reactions.

Publications and Presentations: Multiple by GOG.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/378 (3) Status: Completed

(4) Title: Ovarian Tumors of Low Malignant Potential: A Study of the Natural History and a Phase II Trial of Melphalan and Secondary Treatment with Cisplatin in Patients with Progressive Disease

GOG 72

(5) Start Date: 12/20/83

(6) Est Compl Date: Unknown

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 3

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol

(17) Progress: Three patients, surgical-pathological study only, no adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/380 (3) Status: Completed

(4) Title: A Clinical Pathologic Study of Primary Malignant Melanoma
of the Vulva Treated by Modified Radical Hemivulvectomy
GOG 73

(5) Start Date: 11/1/83

(6) Est Compl Date: 1990

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results:_
c. Number of Subjects Enrolled During Reporting Period:_
d. Total Number of Subjects Enrolled to Date:_
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of
cancer.

(16) Technical Approach: See protocol

(17) Progress: No patients entered.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/353 (3) Status: Ongoing

(4) Title: Evaluation of Cisplatin, Etoposide, and Bleomycin
Induction Followed by Vincristine, Dactinomycin and
Cyclophosphamide Consolidation in Advanced Ovarian
Germ Cell Tumors

GOG 90

(5) Start Date: 9/18/86

(6) Est Compl Date: 1991

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MFD/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/354 (3) Status: Ongoing

(4) Title: Randomized Clinical Trial for the Treatment of Women with
Selected Stage IAi & IAii & IBii Ovarian Cancer (Phase III)
GOG 95

(5) Start Date: 9/22/86

(6) Est Compl Date: 1994

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: MED/Hema/Oncol

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/358 (3) Status: Ongoing

(4) Title: Evaluation of Intraperitoneal Chromic Phosphate After
Negative Second-Look Laparotomy in Ovarian Carcinoma

GOG 93

(5) Start Date: 6/1/87

(6) Est Compl Date: 1992

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/359 (3) Status: Ongoing

(4) Title: Adjunctive Radiation Therapy in Intermediate Risk
Endometrial Carcinoma

GOG 99

(5) Start Date: 6/1/87

(6) Est Compl Date: 1991

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/350 (3) Status: Ongoing

(4) Title: Radiation Therapy vs No Further Therapy in Selected
Patients with Stage IB Invasive Carcinoma of the
Cervix

GOG 92

(5) Start Date: 3/9/88

(6) Est Compl Date: 1992

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/351 (3) Status: Completed

4) Title: A Phase II Study of the Treatment of Stage III and IV
Disease of Advanced Endometrial Carcinoma and All Stages
of Papillary Serious Carcinoma and Clear Cell Carcinoma
of the Endometrium with Total Abdominal Radiation Therapy
GOG 94

(5) Start Date: 12/22/86

(6) Est Compl Date: 1990

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: ___ MAY ___ b. Review Results: ___
c. Number of Subjects Enrolled During Reporting Period: ___ 0 ___
d. Total Number of Subjects Enrolled to Date: ___ 0 ___
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Completed, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/355 (3) Status: Ongoing

(4) Title: Intraperitoneal (SWOG8501) Intraperitoneal Cis-Platinum
and Cyclophosphamide IV vs Intravenous Cis-Platinum
and Cyclophosphamide IV in Patients with Optimal
Stage III Ovarian Cancer

GOG 104

(5) Start Date: 6/15/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators

(11) Key Words:
pelvic neoplasms

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e". None other than expected.

(15) Study Objective: The objective is to participate in the GOG group
in the study of malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Ongoing, one patient living with no evidence of disease.
No adverse effects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/358 (3) Status: Ongoing

(4) Title: Monoclonal Antibody Against Free Beta HCG to Predict
Development of PGTD in patients with Hydaditoform Mole

GOG #100

(5) Start Date: 1/88

(6) Est Compl Date: 1/92

(7) Principal Investigator:
Mark E. Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or s
ponsor for studies conducted under an FDA-awarded IND. May be continued
on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/359 (3) Status: Ongoing

(4) Title: GOG 102A - Master Protocol for Intraperitoneal Drug
Studies in Residual Ovarian Malignancies
after Second-Look Surgery

(5) Start Date: 1/4/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group in the study of
malignancies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/360 (3) Status: Completed

(4) Title: A Phase II Trial of Hydroxurea, DTIC and VP-16
in Patients with Advanced Uterine Sarcomas

87C

(5) Start Date: 3/7/88 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective is to participate in the GOG group in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/351 (3) Status: Ongoing

(4) Title: A Phase II Trial of VP-16 in Patients with Advanced
or Recurrent Uterine Sarcoma

GOG 87D

(5) Start Date: Aug 89 (6) Est Compl Date: 1994

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
VP-16
uterine sarcoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To identify active drugs against each of the two major types of sarcomas which have a high recurrence rate and against which combination chemotherapy has not been effective. VP-16 has been included because it has been shown to have elicited some response in a very small sample and the data suggest the need for study in previously untreated patients.

(16) Technical Approach: This is a non-randomized study which will involve treating an average sample size of 30 evaluable patients per drug. This method allows for rapid replacement of ineffective agents.

(17) Progress: No patients have been enrolled at FAMC to date.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/352 (3) Status: Ongoing

(4) Title: A Phase II Evaluation of Preoperative Chemoradiation
for Patients with Advanced Vulvar Cancer
GOG 101

(5) Start Date: Aug 89 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
preoperative chemoradiation
vulvar cancer

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Approved
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine if using preoperative chemoradiotherapy will obviate the need for pelvic exenteration in patients with advanced vulvar cancer; will its use allow less extensive surgical resection without compromising survival or cure.

(16) Technical Approach: All patients will be treated with split-course radiotherapy to the primary lesion as well as chemotherapy. Only patients with positive groin nodes will receive additional radiotherapy to the groin and pelvic nodes. Four to eight weeks after radiotherapy is completed, all patients will have surgical resection of the primary tumor plus bilateral groin node dissection.

(17) Progress: No FAMC patients enrolled to date on this recently approved protocol.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/354 (3) Status: Ongoing

(4) Title: A Randomized Study of Doxorubicin vs Doxorubicin Plus
Cisplatin in Recurrent Endometrial Adenocarcinoma
Previously Diagnosed as Primary Stage III or IV
(Phase III)
GOG 107

(5) Start Date: Aug 89 (6) Est Compl Date: 6/92

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:
doxorubicin
cisplatin
endometrial adenocarcinoma

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine whether the addition of cisplatin to doxorubicin offers significant improvement in the frequency of objective response, in the duration of progression-free interval and the length of survival as compared with the administration of doxorubicin alone.

(16) Technical Approach: Patients will be randomized to one of the two regimens and will be treated until the maximum tolerated dose of doxorubicin is reached or until there is progression of disease.

(17) Progress: No FAMC patients enrolled.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/356 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Alpha Recombinant
Interferon (aIFN) in Residual Ovarian Carcinoma
(Phase II)
GOG 102F

(5) Start Date: 1989

(6) Est Compl Date: 2/91

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators:

(11) Key Words:
Interferon
carcinoma

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To test the effectiveness of this agent when it
is administered directly into the area where the tumor is localized when
there has been a partial response to Cisplatin.

(16) Technical Approach: 50x10⁶ units of Interferon administered IP in
250ml NS after 1750 ml dialysate solution is given IP via the IP
catheter. Therapy is given weekly for 12 weeks.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/350 (3) Status: Ongoing

(4) Title: Ifosfamide and the Uroprotector Mesna, with or without
Cisplatin, in Patients with Advanced or Recurrent Mixed
Mesodermal Tumors of the Uterus

GOG 108

(5) Start Date: 1990 (6) Est Compl Date: 10/93

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/351 (3) Status: Ongoing

(4) Title: A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

GOG 109

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in teh GOG protocol in the study of Cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/352 (3) Status: Ongoing

(4) Title: A Phase II Trial of Didemnin B in Patients with Advanced Pelvic Malignancies

GOG #26EE

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: c. Number of Subjects Enrolled During Reporting Period: 0

d. Total Number of Subjects Enrolled to Date: 0

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/353 (3) Status: Ongoing

(4) Title: A Phase II Trial of Fazarabine in Patients with
Advanced/Recurrent Pelvic Malignancies
GOG 26GG

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/354 (3) Status: Ongoing

(4) Title: A Phase II Trial of 5-Fluorouracil and Leucovorin in
Advanced Metastatic or Recurrent Pelvic Malignancies

GOG #26HH

(5) Start Date: 1990 (6) Est Compl Date: Undetermined

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/355 (3) Status: Ongoing

(4) Title: Intraperitoneal Administration of Cisplatin (NSC#119875)
and Thiotepa in Residual Ovarian Carcinoma

GOG 102G

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/356 (3) Status: Completed

(4) Title: A Phase III Randomized Study of Cyclophosphamide
(NSC#26271) and Cisplatin (NSC#19875) Versus Taxol
(NSC#125973) and Cisplatin (NSC#119875) in patients
with Suboptimal Stage III and Stage IV Epithelial
Ovarian Carcinoma

GOG 111

(5) Start Date: 1990 (6) Est Compl Date: Unknown

(7) Principal Investigator: Mark E. Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: GYN-ONC Svc (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: MAY b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG protocol in the study
of cancer.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/350 (3) Status: Ongoing

(4) Title: GOG 26II - A Phase II Trial of 5-FU and High Dose
Leucovorin in Patients with Advanced/Recurrent
Pelvic Malignancies

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB-GYN

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date: 1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: One patients entered at FAMC.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/351 (3) Status: Ongoing

(4) Title: GOG 26JJ - A Phase II Trial of Taxol (NSC#125973) in
Patients with Advanced Carcinoma of the Cervix

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB/GYN

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/352 (3) Status: Ongoing

(4) Title: GOG 102H - A Phase II Study of the Intraperitoneal Administration of Recombinant Interleukin-2 in Residual Ovarian Carcinoma

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB/GYN

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/353 (3) Status: Ongoing
(4) Title: GOG 109 - A Comparison of 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy vs Radiation Therapy Alone in Selected Patients with Stage 1A-2, 1B or 2A Carcinoma of the Cervix Following Radical Hysterectomy and Node Dissection

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB-GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/354 (3) Status: Ongoing
-
- (4) Title: GOG 110 - A Randomized Study of Cisplatin vs Cisplatin Plus
Dibromodulcitor (NSC#104800) vs Cisplatin Plus Ifosfamide
and Mesna in Advanced Carcinoma of the Cervix
-
- (5) Start Date: 1991 (6) Est Compl Date:
-
- (7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC
-
- (9) Dept/Svc: OB/GYN (10) Associate Investigators:
-
- (11) Key Words:
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To participate in the GOG group.
-
- (16) Technical Approach: See protocol.
-
- (17) Progress: No patients entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/355 (3) Status: Ongoing

(4) Title: GOG 112 - A Randomized Comparison of Chemoprophylaxis
Using Methotrexate vs Routine Surveillance in Mangement
of High Risk Molar Pregnancy

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG group.

(16) Technical Approach: See protocol.

(17) Progress: One patient entered.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/356 (3) Status: Completed

(4) Title: GOG 26KK - A Phase II Trial of Merbarone (NSC 336628) in Patients with Advanced and Recurrent Endometrial, Cervical and Epithelial Ovarian Carcinoma

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: OB/GYN (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/357 (3) Status: Ongoing

(4) Title: GOG 26LL - A Phase II Trial of Prolonged Oral Etoposide
(VP-16) in Patients with Advanced Pelvic Malignancies

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB/GYN

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 91/358 (3) **Status:** Completed

(4) **Title:** GOG 113 - An Evaluation of Hydroxyurea, 5-FU Infusion and Bolus Cisplatin as an Adjunct to Radiation Therapy in Patients with Stage II-B, III and IV-A Carcinoma of the Cervix and Negative Para-aortic Nodes

(5) **Start Date:** 1991

(6) **Est Compl Date:**

(7) **Principal Investigator:**
Mark Potter, MAJ, MC

(8) **Facility:** FAMC

(9) **Dept/Svc:** OB/GYN

(10) **Associate Investigators:**

(11) **Key Words:**

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** _____

b. **Review Results:** _____

c. **Number of Subjects Enrolled During Reporting Period:** _____

d. **Total Number of Subjects Enrolled to Date:** _____

e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To participate in the GOG studies.

(16) **Technical Approach:** See protocol.

(17) **Progress:** No patients enrolled at FAMC.

Publications and Presentations: None

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FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/359 (3) Status: Ongoing

(4) Title: GOG 87F - A Phase II Trial of Doxorubicin and Ifosfamide
with Mesna in the Treatment of Recurrent or Advanced
Uterine Leiomyosarcomas

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Mark Potter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: OB/GYN

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the GOG studies.

(16) Technical Approach: See protocol.

(17) Progress: One patient enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/350 (3) Status: Ongoing

(4) Title: GOG 26MM: A Phase II Trial of Edatrexate (ETX) in
Gynecologic Malignancies

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: Mark Potter, MAJ, MC (8) Facility: FAMC

(9) Dept of OB-GYN (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG study.

(16) Technical Approach: See protocol.

(17) Progress: No patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/351 (3) Status: Ongoing

(4) Title: GOG 119: A Study of the Use of Provera and Tamoxifen Citrate (NSC #180973) for the Treatment of Advanced, Recurrent or Metastatic Endometrial Carcinoma

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:

(8) Facility: FAMC

Mark Potter, MAJ, MC

(9) Dept of OB-GYN

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the GOG protocol in the study of malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 82/403 (3) Status: Ongoing

(4) Title: Rare Tumor Protocol for Childhood Solid Tumor
Malignancies, Ancillary
POG 7799

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept of Pediatrics (10) Associate Investigators
Thomas Carter, COL, MC
(11) Key Words: Jeffrey Clark, COL, MC
drug therapy Randal Henderson, MAJ, MC

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 5 e.
Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 82/414 (3) Status: Ongoing

(4) Title: NWTs Long Term Follow-Up Study: A Non-therapeutic Study
POG 8158

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold Mosijczuk, COL, MC

(9) Dept/Svc: Pediatrics (10) Associate Investigators

(11) Key Words:
drug therapy

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 0
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons, the study remains open to new patient registrations.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 82/420 (3) Status: Ongoing

(4) Title: Intergroup Rhabdomyosarcoma Study III

POG 8451

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators

Dr. Clark

(11) Key Words:
drug therapy

Dr. Reddy

Dr. Henderson

Dr. Bodlien

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: Four patients have been entered at FAMC. The first patient has relapsed with metastatic disease after having completed the prescribed two years of chemotherapy and has died. Another patient, who entered in 1987 achieved complete remission status of his undifferentiated sarcoma of the pelvis region, but has subsequently died of overwhelming sepsis as a result of severe myelosuppression from chemotherapy; another patient entered in October 1986 had pulmonary metastases of chest and died on 10 July 1990. The other patient who was entered in 1988 with nasopharyngeal rhabdomyosarcoma is currently in complete remission status having completed chemotherapy. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/401 (3) Status: Ongoing

(4) Title: Combined Therapy and Restaging in the Treatment of Stages I, IIA, and IIIA Hodgkins Disease in Pediatric Patients, A Pediatric Oncology Group Phase III Study
POG 8625/26

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold D. Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Reddy
(11) Key Words: drug therapy Dr. Bodlien
Dr. Henderson

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 2
d. Total Number of Subjects Enrolled to Date: 4
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No unusual toxicities have been encountered. The study remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 87/404 (3) Status: Ongoing

(4) Title: A Study of Childhood Soft Tissue Sarcomas (STS) Other
than Rhabdomyosarcoma and Its Variants, A Pediatric
Oncology Group Phase III Study
POG 8653/54

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Askold D. Mosijczuk, COL, MC

(9) Dept/Svc: PED/Hema/Oncol (10) Associate Investigators
Dr. Clark
(11) Key Words: Dr. Reddy
drug therapy Dr. Bodlien

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e".

(15) Study Objective: The objective is to participate in the POG group
in the study of pediatric malignancies.

(16) Technical Approach: See Protocol

(17) Progress: No patients have been entered at Fitzsimons. The study
remains open to new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/400 (3) Status: Ongoing

(4) Title: T Cell#3 Protocol - A Pediatric Oncology Group Phase III Study

POG 8704

(5) Start Date: Dec 1987

(6) Est Compl Date: 1990

(7) Principal Investigator:
Askold D. Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators
B. Vishnu Reddy, LTC, MC
Randal Henderson, MAJ, MC
John M. Bodlien, CPT, MS

(11) Key Words:
T cell ALL

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The one patient entered at FAMC (MP) is an eight-year-old girl who presented with an extremely high white count at diagnosis (852,000) and was found to have T-cell ALL. The patient responded well to initial leukopheresis and chemotherapy according to protocol. She relapsed 8 months from diagnosis and died. Toxicity has been the expected severe myelosuppression. The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 88/408A (3) Status: Ongoing

(4) Title: The Effect of Human/Animal Interaction on Stress
Levels During Outpatient Pediatric Oncology Visits

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: Mary Woolverton, MSW (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators
Askold Mosijczuk, COL, MC

(11) Key Words:
animal interaction
stress reduction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results: Ongoing
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 12
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: a. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's stress level as measured by blood pressure and fingertip temperature; b. Does the presence and interaction with animals during outpatient treatment visits have any measurable effect on the patient's anxiety level (as measured by behavioral questionnaires) or discomfort as measured by the visual analog pain scale).

(16) Technical Approach: Blood pressure, temperature and questionnaire will be used to evaluate stress levels in study subject.

(17) Progress: A total of 12 patients have been entered into the study. Due to investigators' time constraints we have not been able to gather data as projected. Hope to begin enrollment in fall of 1991. FY 92, no response from PI.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 89/401A (3) **Status:** Terminated

(4) **Title:** An Observational Study on the Response of Children to the Presence of a Stuffed Animal VS a Live Animal During a Neuromuscular Exam

(5) **Start Date:** 1988

(6) **Est Compl Date:** 1992

(7) **Principal Investigator:**
Mary Woolverton, MSW
Terri R. Clark, CPT, VC

(8) **Facility:** FAMC

(9) **Dept/Svc:** PEDS/EFMP

(10) **Associate Investigators:**
David Hahn, LTC, MC
Murta Ocha, CPT, VC
Crystal Sherman, NS

(11) **Key Words:**
animal interaction
stress reduction

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** DEC b. **Review Results:**
c. **Number of Subjects Enrolled During Reporting Period:** 9
d. **Total Number of Subjects Enrolled to Date:** 45
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** By introducing an interaction with an animal we may be able to decrease anxiety and lessen the apprehension associated with potentially uncomfortable hospital visits.

(16) **Technical Approach:** See protocol

(17) **Progress:** Administratively terminated by the Laboratory Animal Care and Use Committee because the study has not been updated as requested.

Publications and Presentations: 3 presentations.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/404 (3) Status: Ongoing

(4) Title: Randomized Study of Intensive Chemotherapy (MOPP/ABVD)
+ or - Low Dose Total Nodal Radiation Therapy in the
Treatment of Stages IIB, IIIA-2, IIIB, IV Hodgkin's
Disease in Pediatric Patients
POG 8725

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS/Hemo/Oncol

(10) Associate Investigators:

(11) Key Words:

Dr. Reddy

Dr. Clark

Dr. Henderson

Dr. Bodlien

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG protocol in the study
of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: No patients have been entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/402A (3) Status: Ongoing

(4) Title: Training for Pediatricians in Emergency Procedures

(5) Start Date: 1990

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Brian Carter, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Neonatal/PEDS

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To train pediatricians in invasive emergency procedures.

(16) Technical Approach: Goat, swine, and rabbits are to be used for training in intubation, femoral venous and arterial cutdown procedures, thoracostomy tube placement, and percutaneous jugular venous catheter placement.

(17) Progress: Departmental training program's future uncertain.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/405 (3) Status: Completed

(4) Title: Followup of the NICU Graduate in Military Medical Facilities

(5) Start Date: 1990

(6) Est Compl Date: 1991

(7) Principal Investigator:
Beverly Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Newborn/PEDS

(10) Associate Investigators:
Brian S. Carter, MAJ, MC

(11) Key Words:
NICU graduate follow-up

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: APRIL b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 204
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance of NICU graduates in military medical facilities.

(16) Technical Approach: Information retrieved through questionnaire sent to every military facility serving a pediatric population.

(17) Progress: Information from questionnaire is currently being assessed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/406 (3) Status: Ongoing

(4) Title: POG 8788 Intergroup Rhabdomyosarcoma Study IV: A Pilot Study for Clinical Group III Disease

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: PEDS (10) Associate Investigators:

(11) Key Words:

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/407 (3) Status: Ongoing

(4) Title: POG 8821 AML#3: Intensive Multiagent Therapy vs Autologous Bone Marrow Transplant Early in 1st CR for Children with Acute Myelocytic Leukemia

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/408 (3) Status: Ongoing

(4) Title: POG 8823/24 Recombinant Alpha Interferon in Childhood
Chronic Myelogenous Leukemia

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, one patient enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/409 (3) Status: Ongoing

(4) Title: POG 8827 Treatment of Children with Hodgkin's Disease
in Relapse - Phase II

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients entered at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/410 (3) Status: Ongoing

(4) Title: POG 8829 A Protocol for a Case-Control Study of Hodgkin's Disease in Childhood: A Non-Therapeutic Study

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____

b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/412 (3) Status: Ongoing

(4) Title: POG 8850 Evaluation of Vincristine, Adriamycin, Cyclophosphamide, and Dactinomycin with or without the Addition of Ifosfamide and Etoposide in the Treatment of Patients with Newly Diagnosed Ewing's Sarcoma or Primitive Neuroectodermal Tumor of Bone

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/413 (3) Status: Ongoing

(4) Title: POG 8889 Intergroup Rhabdomyosarcoma Study-IV Pilot
Study for Clinical Group IV Disease

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/414 (3) Status: Ongoing

(4) Title: POG 8828 Late Effects of Treatment of Hodgkin's Disease:
A Pediatric Oncology Group Non-Therapeutic Study

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:
quality of life
questionnaire

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer treatment.

(17) Progress: Open to patient accrual. Two patients enrolled and questionnaires completed. Next quality of life questionnaire not due for 3 years.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 90/415 (3) Status: Ongoing

(4) Title: POG 8650 National Wilms' Tumor Study - 4 (NWTIS-4), A
Pediatric Hematology-Oncology Group Phase III Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:
wilm's tumor

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: SEP b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 2
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in POG.

(16) Technical Approach: To determine the most effective cancer
treatment.

(17) Progress: Open to patient accrual, two patient enrolled at FAMC,
alive and doing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/400 (3) Status: Ongoing

(4) Title: Normative Electrocardiographic Data in Healthy Newborns and Infants Living at Intermediate High Altitude

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
James Schroeder, MAJ, MC

(8) Facility: FAMC, Aspen and
Leadville, CO

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:
Herb Whitley, MAJ, MC
Michael Schaffer, MD
Robert Wolfe, MD

(11) Key Words:
newborns
altitude
EKG

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: __Nov__ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To determine normal values of heart rate, PR interval, QRS complex duration, QT interval, P wave axis, frontal plane QRS axis, T wave axis, and morphology of precordial QRS complexes and T waves in healthy infants carried in utero and born at altitude, up to the age of 12 months.

(16) Technical Approach: We will obtain EKGs from healthy infants at a variety of ages from birth to 12 months, in conjunction with routine newborn nursery evaluations and well-child clinic visits at three different altitude sites. Approximately 100 subjects will be studied.

(17) Progress: Due to administrative difficulties and logistics, the Aspen and Leadville portions of the study have not progressed to the point of beginning data collection; therefore, the entire project is on indefinite hold. No data collection has begun at Fitzsimons, pending developments at the outlying sites.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/401A (3) Status: Ongoing

(4) Title: Pediatric Intubation Training Using the Ferret Model

(5) Start Date: 1991

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Beverly Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:
John Kinsella, MAJ, MC

(11) Key Words:
training

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____

b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skills of neonatal endotracheal intubation.

(16) Technical Approach: Per protocol approved by LACUC 6 Dec 90.

(17) Progress: Anticipate an animal lab under this protocol in the summer of 1992.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 91/403 (3) Status: Ongoing
-
- (4) Title: Evaluation of Test of Cure Using a DNA-Probe Test for Neisseria Gonorrhea
-
- (5) Start Date: 1990 (6) Est Compl Date: 1992
-
- (7) Principal Investigator: John Hanks, CPT, MC (8) Facility: FAMC
-
- (9) Dept/Svc: Pediatrics (10) Associate Investigators: Clifford Butler, SM, DAC
Christine Scott, CPT, MC
-
- (11) Key Words: DNA probe
gonorrhoea
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report
-
- (14) a. Date, Latest IRC Review: Dec b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 3
d. Total Number of Subjects Enrolled to Date: 20
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"
-
- (15) Study Objective: To determine that the Gen-Probe PACE 2 system is a sensitive and specific predictor of gonorrhea infection of the female cervix or male urethra in the young adult (age 13-28 yrs). Also to determine if the Gen-Probe PACE 2 system can be used to test for cure of gonorrhea following treatment, and if so, the best time to test after treatment is completed (e.g. 7,14,21, or 28 days following treatment).
-
- (16) Technical Approach: Specimens from 30-50 patients with positive gonococcal cultures will be evaluated. This study is a test of a test. Patients will be treated in the usual manner and will be re-tested on their followup visits.
-
- (17) Progress: Between Feb 91 and Oct 91, 650 total screening cultures, 20 (3.1%) positive GC cultures, 71 (85%) enrolled in study. Results: Test of cure obtained between 6-11 days after treatment. (Median = 7 days). All 17 have shown negative GC culture and negative DNA probe. Three patients enrolled since end of FY 91. Awaiting results on the recent three.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/404 (3) Status: Ongoing

(4) Title: POG 8615 - A Phase III Study of Large Cell Lymphomas in Children and Adolescents - A Comparison of Two Treatment Regimens - ACOP+ versus APO

(5) Start Date: 1991 (6) Est Compl Date:

(7) Principal Investigator: Askold Mosijczuk, COL, MC (8) Facility: FAMC

(9) Dept/Svc: Pediatrics (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol

(17) Progress: Ongoing, no patients enrolled.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/405 (3) Status: Terminated

**(4) Title: Can Spirometry Significantly Impact the Healthy Adolescent
in Influencing Cessation**

(5) Start Date: 1991

(6) Est Compl Date: 1992

**(7) Principal Investigator:
J.H. Walker, CDR, MC, USN**

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

**(11) Key Words:
smoking cessation
spirometry**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
**e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"**

**(15) Study Objective: To determine the effectiveness in various
approaches to adolescent smoking cessation.**

**(16) Technical Approach: The study involves comparing two different
techniques of presentation to encourage adolescents to quit smoking.
Spirometry will be used in the study group.**

**(17) Progress: No progress due to training commitments of the
investigator.**

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/406 (3) Status: Ongoing

(4) Title: POG 9000 - POG Acute Lymphocytic Leukemia in Childhood #15
Classification: A Non-therapeutic Study

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/407 (3) Status: Ongoing

(4) Title: POG 9005 - Dose Intensification of Methotrexate and
6-Mercaptopurine for Acute Lymphocytic Leukemia in
Childhood: A Phase III Study

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/408 (3) Status: Ongoing

(4) Title: POG 9006 - Up-Front Intensive 6-MP/Methotrexate versus
Up-Front Alternating Chemotherapy for Childhood Acute
Lymphocytic Leukemia: A Phase III Study

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/409 (3) Status: Ongoing

(4) Title: POG 9046 - Molecular Genetic Analysis of Wilms' Tumor

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Askold Mosijczuk, COL, MC

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To participate in the POG studies.

(16) Technical Approach: See protocol.

(17) Progress: Ongoing, no patients enrolled at FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 921 (2) Protocol #: 91/410 (3) Status: Completed

(4) Title: Studies of the Neurologic Examination of Young Infants

(5) Start Date: 1991

(6) Est Compl Date: 1992

(7) Principal Investigator:
Beverly Anderson, MAJ, MC

(8) Facility: FAMC

(9) Dept/Svc: Ped/Newborn

(10) Associate Investigators:
Patricia Ellison, MD, UCHSC
Bonnie Camp, MD, UCHSC

(11) Key Words:
Neoneuro

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: May b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The purpose of this study is to provide normative data and scoring for an assessment method (which we call the Neoneuro) which we have previously developed. This will help clinicians to appropriately evaluate and score infants of these ages.

(16) Technical Approach: In this collaborative study with UCHSC 500 neurological evaluations with as many subjects as possible will be performed by trained nurse practitioners. The scores for all infants (normal and abnormal) in thses new age groupings will then be reviewed for descriptive statistics for itmes, factors and total scores: frequencies, means, standard deviations, skews, and kurtoses.

(17) Progress: Evaluations have recently begun at both institutions.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/411 (3) Status: Ongoing

**(4) Title: POG 8945 An Intergroup Protocol for the Treatment of
Childhood Hepatoblastoma and Hepatocellular Carcinoma**

(5) Start Date: 1991

(6) Est Compl Date:

**(7) Principal Investigator:
Askold Mosijczuk, COL, MC**

(8) Facility: FAMC

(9) Dept/Svc: Pediatrics

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____1_____
**e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"**

(15) Study Objective: To participate in the POG protocols.

(16) Technical Approach: See Protocol

**(17) Progress: Ongoing, one patient enrolled on study and has
completed four courses of chemotherapy. Doing well.**

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/400 (3) Status: Ongoing

(4) Title: POG 9151 IRS-IV Stage 2 and 3 Disease

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/401 (3) Status: Ongoing

(4) Title: POG 9153 Intergroup Rhabdomyosarcoma Study Laboratory
Evaluation of Tumor Tissue

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: OCT b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/402 (3) Status: Ongoing

(4) Title: Restandardization of Bayley Scales of Infant Development

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator: Majorie Feinberg, OTR, DAC EFMP

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results: c. Number of Subjects Enrolled During Reporting Period: 30 d. Total Number of Subjects Enrolled to Date: 30 e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To recruit and test 10 subjects per examiner using the updated Bayley scale of infant development as part of national restandardization effort.

(16) Technical Approach: Recruited subjects from well baby clinic. Scheduled appointments for teting. Tested subjects. Submitted test results to psychological corporation.

(17) Progress: The study is ongoing.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/403 (3) Status: Ongoing

(4) Title: POG 9150 IRS-IV Stage 1 Disease

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/404 (3) Status: Ongoing

(4) Title: POG 9152 IRS-IV Stage 4 and/or Clinical Group IV Disease

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/405 (3) Status: Ongoing

(4) Title: Hypertrophic Cardiomyopathy and Disproportionate Septal Hypertrophy in Newborns

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Brian Carter, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators

(11) Key Words:
newborn
cardiac hypertrophy

MAJ Steven Neish, MC

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV ' b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 17
d. Total Number of Subjects Enrolled to Date: 17
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Determine presence of hyperinsulinemia in macrosomic infants not born to diabetic women and assess any relationship of such macrosomia and hyperinsulinemia with cardiac hypertrophy.

(16) Technical Approach: Cord blood analysis and newborn echocardiogram.

(17) Progress: 17 total enrolled, lab lost/discarded samples of cord blood on 6, echocardiogram not done on 2 others leaving 9 completed studies. Need to enroll and complete studies on at least 11 more subjects.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/406 (3) Status: Ongoing

(4) Title: POG 9031 Treatment of Children with High-Stage
Medulloblastoma: Cisplatin/VP-16 Pre- vs Post-
Irradiation: A Phase III Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: DEC b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/407 (3) Status: Ongoing

(4) Title: POG 9135 Pre-Radiation Chemotherapy for Children with
Supratentorial Malignant Gliomas and Poorly-
Differentiated Embryonal Tumors. A Randomized Phase
II Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/408 (3) Status: Ongoing

(4) Title: POG 9136 Phase I/II Dose Escalating Trial of Hyperfractionated Irradiation in the Treatment of Supratentorial Malignant Tumors of Childhood

(5) Start Date: 1992 (6) Est Compl Date:

(7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JAJ b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/409 (3) Status: Terminated

**(4) Title: A Comparative Study of the Safety and Efficacy of
Clarithromycin and EryPed (Erythromycin Ethylsuccinate)
Suspension in the Treatment of Children with Community-
Acquired Pneumonia**

(5) Start Date: 1992

(6) Est Compl Date:

**(7) Principal Investigator:
Frederic Bruhn, COL, MC**

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

(14) a. Date, Latest IRC Review: JAN b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

**e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".**

(15) Study Objective:

(16) Technical Approach:

(17) Progress: No patients entered, study terminated.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/410 (3) Status: Ongoing

(4) Title: POG 9061 The Treatment of Isolated Central Nervous System
Leukemia - A Pediatric Oncology Group-Wide Pilot Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/411 (3) Status: Ongoing

(4) Title: POG 9110 SIMAL #6 Rotational Drug Therapy After First Marrow Relapse of All-Group-Wide Pilot

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/412 (3) Status: Ongoing

(4) Title: POG 9132 Hyperfractionated Irradiation for Posterior
Fossa Ependymoma. A Phase II/III Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/413 (3) Status: Completed

(4) Title: POG 9139 A Dose-Escalating Study of Cisplatin, Used Concomitantly with Hyperfractionated Irradiation in the Treatment of Children with Newly-Diagnosed Brain Stem Gliomas. A Phase I Study

(5) Start Date: 1992

(6) Est Compl Date:

**(7) Principal Investigator:
George Maher, MAJ, MC**

(8) Facility: FAMC

(9) Dept of

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: MAR b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study is closed for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/414 (3) Status: Ongoing

(4) Title: POG 9259 Carboplatin in the Treatment of Newly-Diagnosed Metastatic Osteosarcoma or Unresectable Osteosarcoma: A POG Phase III Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/415 (3) Status: Status

(4) Title: POG 9107 Infant Leukemia Protocol: A Pediatric
Oncology Groupwide Pilot Study

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/416 (3) Status: Ongoing

(4) Title: Improved Group A Strep Growth in Selective Media As an Indicator of True Infection

(5) Start Date: 1992 (6) Est Compl Date: 1994

(7) Principal Investigator: Frederic Bruhn, COL, MC (8) Facility: FAMC

(9) Dept of PEDS (10) Associate Investigators
Robert Wittler, MAJ, MC

(11) Key Words:
group A strep

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To demonstrate increased recovery of Group A beta hemolytic streptococci (GABS) on selective media (Sheep blood agar supplemented with trimethoprim-sulfamethoxazole, i.e., SBA-SXT) compared to standard media (sheep blood agar, SBA), and to correlate increased recovery of GABS with "true" infection versus a carrier state.

(16) Technical Approach: Approximately 300 patients ages 5-15 will have throat culture and venopuncture as part of this multi-institutional study.

(17) Progress: No patients entered, awaiting lab materials from the Children's hospital.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

- (1) Date: 30 Sep 92 (2) Protocol #: 92/417 (3) Status: Ongoing
- (4) Title: Protocol for the Treatment of Newly Diagnosed Osteogenic Sarcoma in Children, Adolescents, and Adults Incorporating Intra-arterial Cisplatin and Prolonged Systemic Infusion Adriamycin
- (5) Start Date: 1992 (6) Est Compl Date:
- (7) Principal Investigator: George Maher, MAJ, MC (8) Facility: FAMC
- (9) Dept of PEDS\Onc (10) Associate Investigators
- (11) Key Words:
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
- (14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: 1
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
- (15) Study Objective: Determine tolerance of intra-arterial cisplatin in pediatric patients, evaluate response of the primary tumor to pre-op intra-arterial cisplatin.
- (16) Technical Approach: Pre-op chemo with I.V. adriamycin and intra-arterial cisplatin followed by surgery followed by additional chemotherapy.
- (17) Progress: One patient responded well to pre-op chemo, had surgery and now may have relapsed on maintenance chemo.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/418 (3) Status: Ongoing

(4) Title: POG 8617 Therapy for B-Cell Acute Lymphoblastic Leukemia
and Advanced Diffuse Undifferentiated Lymphomas

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of
pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/419 (3) Status: Ongoing

(4) Title: POG 9225 Study for Advanced-Stage Hodgkin's Disease

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/420 (3) Status: Ongoing

(4) Title: POG 9233/34 A Phase III Randomized Trial of Standard vs Dose-Intensified Chemotherapy for Children 3 Years of Age with a CNS Malignancy Treated with or without Radiation Therapy

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/421 (3) Status: Ongoing

(4) Title: POG 9243 Treatment for Children with Intermediate-Risk Neuroblastoma: POG Stage B (All Ages) and Stages C, D, and DS (365 Days at Diagnosis)

(5) Start Date: 1992

(6) Est Compl Date:

(7) Principal Investigator:
George Maher, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Onc

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To participate in the POG protocol in the study of pediatric malignancies.

(16) Technical Approach: See protocol

(17) Progress: The study remains open for new patient entry.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/422 (3) Status: Ongoing

(4) Title: Family History of Growth and Pubertal Development in Children with Constitutional Delay

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: John Hanks, CPT, MC (8) Facility: FAMC

(9) Dept of PEDS/Adol (10) Associate Investigators

(11) Key Words:
constitutional delay
delayed puberty

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:___230 questionnaires___
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Compare pertinent information.

(16) Technical Approach: Use of identical questionnaires in families with children with and without constitutional delay.

(17) Progress: About 700 questionnaires given out, about 350 returned. Project is progressing well.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/423 (3) Status: Ongoing

(4) Title: Development of a Placental Trophoblast Cell Culture for the in Vitro Study of Placental Metabolism

(5) Start Date: (6) Est Compl Date: 1997

(7) Principal Investigator: Brian Carter, MAJ, MC (8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators

Ron Jackson, Ph.D

Donald Mercill, DAC

Phil Vaughan, M.D., UCHSC

Fred Battaglia, M.D., UCHSC

(11) Key Words:
tissue culture
placental trophoblast

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To develop an in vitro placental trophoblast culture for human placental trophoblast to study basic normal and abnormal metabolism.

(16) Technical Approach: In vitro cell culture; tracer studies with stable or radioactive isotope labelled substrates.

(17) Progress: Materiel now in place; cell lines maintained; first preparation scheduled for October.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/424 (3) Status: Completed

(4) Title: Military Physician Survey: Ethical Concerns During
Operation Desert Storm

(5) Start Date:

(6) Est Compl Date: 1992

(7) Principal Investigator:
Brian Carter, MAJ, MC

(8) Facility: FAMC

(9) Dept of PEDS/Newborn

(10) Associate Investigators

(11) Key Words:

ethics

desert storm

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 360
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective: Survey of active duty physicians deployed to the
Persian Gulf for Operation Desert Storm and their concern regarding
medical ethics issues.

(16) Technical Approach: Mailed survey.

(17) Progress: 600 mailed, 360 returns (60%); data analyzed and paper
submitted for presentation at Joint Services Conference on professional
ethics.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 80/602 (3) Status: Ongoing

(4) Title: I.V. Administration of 131-I-6-B Iodomethylnorcholesterol (NP-59) for Adrenal Evaluation and Imaging

(5) Start Date: 1980

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
Morakinyo A.O. Toney, LTC, MC

(8) Facility: FAMC

(9) Dept of Radiology/Nuc.Med.

(10) Associate Investigators

(11) Key Words:
adosterone
adrenal glands

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: NOV _____ b. Review Results: Ongoing____
c. Number of Subjects Enrolled During Reporting Period: 2_____
d. Total Number of Subjects Enrolled to Date: 33_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

(16) Technical Approach: Each patient will be studied while taking Lugol's or SSKI to protect thyroid. Some patients will have adrenal function suppressed with Dexamethasone. Following a 2 millicurie dose of NP-59, each patient will be scanned at day 3 and possibly day 5 and 7.

(17) Progress: Two patients were treated with NP-59 during this period. Both were negative.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

-
- (1) Date: 30 Sep 92 (2) Protocol #: 92/600 (3) Status: Ongoing
-
- (4) Title: CT (Computerized Tomography) Detected Coronary Artery Calcification in Adult Patients Under Age Sixty and Its Relationship to Significant Coronary Artery Stenosis. A Radiologic Pathologic Correlation Study
-
- (5) Start Date: 1992 (6) Est Compl Date: 1994
-
- (7) Principal Investigator: Fred Caruso, CPT, MC (8) Facility: FAMC
-
- (9) Dept of Radiology (10) Associate Investigators
-
- (11) Key Words:
computerized tomography
coronary artery calcifications
-
- (12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.
-
- (14) a. Date, Latest IRC Review: FEB b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".
-
- (15) Study Objective: To enable radiologists to more confidently alert the clinician on the presence and significance of this incidental chest CT finding.
- (16) Technical Approach: Prospective radiologic pathologic correlation.
- (17) Progress: Protocol requires revision for IRC approval. None to date due to boards preparation.
- Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/601 (3) Status: Ongoing

(4) Title: Pontine Lesions on Screening MR (Magnetic Resonance)
Imaging of the Brain: Correlation with Cardiovascular
Risk Factors

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Thomas Damiano, MAJ, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators
Charles Truwit, MAJ, MC

(11) Key Words:
pontine lesions
cardiovascular risk factors
magnetic resonance imaging

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAR b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date:

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: This study is designed to determine the causes, and therefore the potential clinical significance of pontine lesions detected on screening MR imaging examinations of the brain.

(16) Technical Approach: Initially 100 patients will be taken from the population of patients referred to the FAMC Dept of Radiology for cranial MR imaging. A questionnaire will be administered. Power analysis will be performed to determine the number required for the study.

(17) Progress: No progress to date due to lengthy TDY of principal investigator.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/602 (3) Status: Ongoing

(4) Title: Focal Cerebral Ischemia in Severe Acute Asthma and Its Association with Beta-Adrenergic Agonists

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Stephen Yoest, CPT, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators

(11) Key Words:
asthma
blood flow
MRI

Dr. Truwit
Dr. Rosen
Dr. Graham

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To see if children having acute asthma attacks have areas of decreased blood flow to the brain which may be detected by magnetic resonance imaging (MRI) of the brain.

(16) Technical Approach: Obtain MRI scan of brain after standard and routine asthma treatment has taken place in either the emergency room, pediatric ward of intensive care unit.

(17) Progress: No progress.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/603 (3) Status: Completed

(4) Title: The Magnavist Injection Post Marketing Surveillance Study

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: Luis Gonzales, MAJ, MC (8) Facility: FAMC

(9) Dept of Radiology (10) Associate Investigators

(11) Key Words:
contrast reaction

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: June b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 81
d. Total Number of Subjects Enrolled to Date: 81
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To further evaluate magnavist as a safe contrast agent.

(16) Technical Approach: Close monitoring of patients during and immediately after procedure with F/U (24H0); calls to patients to check for delayed reaction.

(17) Progress: No contrast reactions evidenced.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/650A (3) Status: Ongoing

(4) Title: Study of Hemoglobin and Red Cell Metabolism in Didelphis marsupialis

(5) Start Date: 1993

(6) Est Compl Date: Indefinite

(7) Principal Investigator:
N.C. Bethlenfalvay, MD

(8) Facility: FAMC

(9) Dept/Svc: Primary Care

(10) Associate Investigators:
J.E. Lima, DAC

(11) Key Words:
hemoglobin
red cell metabolism

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: 1) To establish normal values for hematology, red cell metabolism, red cell survival, and immunology of the South American Opossum, thereby providing a comparison to data observed in the North American Opossum already studied under protocol 80/650. 2) To determine if levels of red cell nucleotides and ADA are dissimilar in South American opossum, the progenitor of the N.A. opossum.

(16) Technical Approach: Per protocol approved by LACUC on 19 Feb 91.

(17) Progress: Through a Brazilian representative to the Pan American Health Organization, contact was established with Conselho Nacional de Desenvolvimento Cientifico e Tecnologico, Brasilia, Brasil a potential source of species D. marsupialis for shipment to FAMC.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/651A (3) Status: Ongoing

(4) Title: A Prevention of dATP Synthesis in Red Blood Cells of
Didelphia virginiana Through Administration of ADGEN

(5) Start Date: 1991

(6) Est Compl Date: 1993

(7) Principal Investigator:
N.C. Bethlenfalvay, MD

(8) Facility: FAMC

(9) Dept/Svc: Primary Care

(10) Associate Investigators:
J.E. Lima, DAC

(11) Key Words:
red blood cells

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: To establish similarities or differences between
human and *D. virginiana* red cells in their response to ADAGEN at
preventing the accumulation of dATP in newly formed RBC.

(16) Technical Approach: Per protocol approved by LACUC 19 Feb 91.

(17) Progress: In contrast to human RBC, there was only a slight
decline of dATP in opossum red cells well past the lifespan of these
cells. A significant portion of deoxyadenosine in plasma was found to
be incorporated into ATP due to a novel pathway of ATP synthesis.
Phosphorylation of deoxyadenosine to dATP in opossum red cells is
several orders of magnitude greater than that seen in human red cells.
There are three papers in preparation as a result of this protocol.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 92/650 (3) **Status:** Ongoing

(4) **Title:** Patient Education Through Record Sharing

(5) **Start Date:** 1992

(6) **Est Compl Date:** 1994

(7) **Principal Investigator:**
Stuart Smith, M.D., DAC

(8) **Facility:** FAMC

(9) **Dept of PCCM**

(10) **Associate Investigators**

(11) **Key Words:**
patient education
record sharing

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report.

(14) a. **Date, Latest IRC Review:**_____ b. **Review Results:**_____
c. **Number of Subjects Enrolled During Reporting Period:**_____
d. **Total Number of Subjects Enrolled to Date:**_____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) **Study Objective:** To evaluate the role of patients in cost/quality.

(16) **Technical Approach:** Partial record sharing.

(17) **Progress:** All steps completed to permit anticipated start.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/702 (3) **Status:** Terminated

(4) **Title:** The Impact of Practice at Fitzsimons Army Medical Center
Upon Registered Nurses Professional Role Conception

(5) **Start Date:** (6) **Est Compl Date:** 1992

(7) **Principal Investigator:** A.J. Frelín, COL, AN (8) **Facility:** FAMC

(9) **Dept/Svc:** Nursing (10) **Associate Investigators:**

(11) **Key Words:**
registered nurses
role conception

(12) **Accumulative MEDCASE:*** (13) **Est Accum OMA Cost:***
*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** JULY b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** _____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** a) Compare the role conception of neophyte RNs upon their assignment to FAMC and one year after assignment. b) Compare the role conception of experienced RNs upon their assignment to FAMC and one year after assignment. c) Assess similarities and dissimilarities between the two groups. d) Evaluate especially items of role discrepancy among all groups with the intent of making decisions regarding possible system changes which could decrease role conflict and impact positively on retention.

(16) **Technical Approach:** Comparative study using questionnaires distributed over an 18-month period.

(17) **Progress:** First anniversary of data collection has occurred. Analysis of data collected showed no difference.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 91/701A (3) **Status:** Ongoing

(4) **Title:** Suturing Techniques for FAMC Personnel

(5) **Start Date:** 1991

(6) **Est Compl Date:**

(7) **Principal Investigator:**
Debra M. Castellan, LTC, AN

(8) **Facility:** FAMC

(9) **Dept/Svc:** Nursing

(10) **Associate Investigators:**

(11) **Key Words:**

(12) **Accumulative MEDCASE:***

(13) **Est. Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:**_____ b. **Review Results:**_____
c. **Number of Subjects Enrolled During Reporting Period:**_____
d. **Total Number of Subjects Enrolled to Date:**_____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** Training professional and paraprofessional nursing personnel at FAMC in basic suturing techniques.

(16) **Technical Approach:** Training will consist of a didactic classroom component and practical proficiency component. The lesson plan of the protocol approved by LACUC on 16 Apr 91 will be followed when conducting both components.

(17) **Progress:** Part of the EMT continuing certification is suture techniques. This certification is obtained within the animal lab. A specific physician has been identified within the Emergency Medical Services to provide hands on instruction. It is felt with an established POC and specific training day tht the section will be able to better utilize the DCI facilities.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/702 (3) Status: Ongoing

(4) Title: Pilot Study for Psychometric Properties of Selected Tools
for Pain Assessment and Management in Children

(5) Start Date: 1991 (6) Est Compl Date: 1992

(7) Principal Investigator: Catherine Johnson, LTC, AN (8) Facility: FAMC

(9) Dept/Svc: Nursing (10) Associate Investigators:
Loretta Forlaw, LTC, AN
(11) Key Words: Sue Wood, MAJ, AN
pain assessment Jeff Jones, MAJ, AN

(12) Accumulative MEDCASE:* (13) Est. Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: June b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: Pilot study to examine the feasibility of a
protocol for pain assessment and management with hospitalized children
ages birth through 18 years and to estimate the psychometric properties
of the related tools.

(16) Technical Approach: The descriptive correlational design will
involve implementing the Policy for Pain Assessment and Management which
outlines a protocol or systematic pain assessment and recommends nursing
actions for pain relief in accordance with existing physicians' orders.

(17) Progress: The pilot study has been completed and the preliminary
data analyzed. The data indicates that some modification to the Child
Pain Scale needs to occur prior to the implementation of the tool in the
funded 5 year study. Evaluation of this tool indicated most nurses
thought it contained relevant content but it was too lengthy, complex,
and cumbersome to use in its current form.

The Pain Experience History forms were felt by the nurses to be
excellent but the information obtained may need to be transferred to
forms at the bedside.

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The Poker Chip Tool was felt to be easy to use and easy to obtain valid information on the child's pain but there was concern about giving the tool to the child at the same time that the parent evaluated the child's pain using the tool. Perhaps the child would feel the nurse did not believe the child's assessment of their own pain. Orientation to the tools and program was felt to be appropriate in time and content but more support during their study for questions/problems may be needed.

The Pain Flow Sheet was assessed to be positive but may also need some minor changes to make the form easier and faster to use.

Although the collection of data for the pilot study has been completed, the Child Pain Scale is being revised and we request that the study be continued to allow for retesting of this tool here. There is minimal risk associated with this tool as it measures a child's behavioral responses to pain and involves mostly observation.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/700 (3) Status: Terminated

(4) Title: Effect of Pre-Surgical Education and Relaxation-
Stress/Pain Control Training on Post Surgical Recovery

(5) Start Date: (6) Est Compl Date:

(7) Principal Investigator: (8) Facility: FAMC
Loretta Forlaw, COL, AN

(9) Dept of Nursing (10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date:
e. Note any adverse drug reactions reported to the FDA or sponsor for
studying under an FDA-awarded IND. May be continued on a separate
sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: The IRC reviewed and approved the study with
stipulations which to date have not been met. This protocol was
submitted for DA Nursing Research Funds. Funds were denied; therefore,
the study will not be performed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/701 (3) Status: Ongoing

(4) Title: Post-Op Pain Control: Randomized Comparison of PCA, PCA Plus Continuous Infusion, and Regularly Scheduled Nurse Administered Intravenous Morphine Sulfate

(5) Start Date: (6) Est Compl Date: 1993

(7) Principal Investigator: Rose Gates, LTC, AN (8) Facility: FAMC

(9) Dept of Nursing (10) Associate Investigators

(11) Key Words:
pain
pca

LTC Daniel Tell
CPT Janet Wilson
MAJ Mary Miller
LTC Phillip Mallory

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: JUNE b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To compare the efficacy of post-op pain control using PCA, PCA plus continuous infusion, and regularly scheduled nurse administered medications.

(16) Technical Approach: Use of PCA devices.

(17) Progress: None - plan to start enrolling patients in mid-October.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/702 (3) Status: Terminated

(4) Title: The Effectiveness of Interventions to Reduce the Depression and Stress Associated with Antepartum Hospitalization

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Carol Rupkalvis, LTC, AN

(8) Facility: FAMC

(9) Dept of Nursing

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____

b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: This protocol was submitted for DA Nursing Research Funds. Funds were denied; therefore, the study will not be performed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/800A (3) Status: Ongoing

(4) Title: Survey of Tick Vectors and Wild Rodents for the Presence of Borrelia burgdorferi in the Deer Tick, Ixodes pacificus, and in the Black-legged Tick, Ixodes scapularis

(5) Start Date: 1991

(6) Est Compl Date:

(7) Principal Investigator:
Lester Hale, Ph.D.

(8) Facility: FAMC

(9) Dept/Svc: USA Environ.Hyg.

(10) Associate Investigators:
Michael Quintana, CPT, MS

(11) Key Words:
ticks
Lyme disease

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The objective of this study is to survey for the above cited tick vectors, and to determine by selected methods the presence of Borrelia burgdorferi in tick vectors and wild rodents on military installations within the USAEHA-W support area. The USAEHA-W has been tasked by the US Army Health Services Command to conduct surveillance of Lyme disease on Army installations within CONUS to determine the health threat posed to the military community.

(16) Technical Approach: Per protocol approved by LACUC on 18 June 1991.

(17) Progress: Ixodes pacificus were found at Camp Pendleton. Positive ticks for Borrelia burgdorferi have been identified.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/801A (3) Status: Ongoing

(4) Title: Studies of the Metabolic Adaptation in Response to Chronic Severe Hypoxia in the Pregnant Sheep

(5) Start Date: 1991

(6) Est Compl Date: 1994

(7) Principal Investigator:
S. Gwynn Geddie, MAJ, MC

(8) Facility: UC Perinatal Research
Facility located at FAMC

(9) Dept/Svc: Ped

(10) Associate Investigators:
Frederick Battaglia, MD

(11) Key Words:
hypoxia
metabolic adaptations

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To study the metabolic adaptations which occur under chronic hypoxia.

(16) Technical Approach: Per protocol approved by LACUC on 18 Jul 91.

(17) Progress: No progress. Funding was not approved, no response from PI.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/900 (3) Status: Ongoing

(4) Title: Evaluation of a Phase I Coxiella burnetii Vaccine (IND 610)
for Immunization Against Q Fever

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Steven Boyea, CPT, MC (8) Facility: FAMC
US Army Health Clinics
Dugway Proving Grounds
Dugway, Utah 84022

(9) Dept/Svc: (10) Associate Investigators: None

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results: c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk workers.

(16) Technical Approach: Administered by U.S. Army Research Institute for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/901 (3) Status: Ongoing

(4) Title: Continued Evaluation of the Safety and Effectiveness
of Venezuelan Equine Encephalomyelitis Vaccine, TC-83
Live, Attenuated, NDBR-102, Lot 4 in At-Risk Personnel
IND 142

(5) Start Date:
Unknown

(6) Est Compl Date:
Inactive at present time.
IND protocol current.

(7) Principal Investigator:
Steven Boyea, CPT, MC

(8) Facility: FAMC
US Army Health Clinic, DPG

(9) Dept/Svc:

(10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 0
d. Total Number of Subjects Enrolled to Date: 15
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk
workers.

(16) Technical Approach: Administered by U.S. Army Research Institute
for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/902 (3) Status: Ongoing

(4) Title: Evaluation of New Lots of Tularemia Vaccine, Protocol B:
Comparative Assessment of Francisella tularensis
Vaccine, Live, NDBR 101, IND 157

(5) Start Date: Unknown (6) Est Compl Date: Ongoing

(7) Principal Investigator: Steven Boyea, CPT, MC (8) Facility: FAMC
Dugway Proving Grounds
US Army Health Clinic

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jan b. Review Results:
c. Number of Subjects Enrolled During Reporting Period: 7
d. Total Number of Subjects Enrolled to Date: 23
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"

(15) Study Objective: Surveillance program to protect high risk
workers.

(16) Technical Approach: Administered by U.S. Army Reserach Institute
for Infectious Disease.

(17) Progress: Endpoint of this study has not been reached.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 89/903 (3) **Status:** Ongoing

(4) **Title:** Evaluation of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated. Protocol B: Continued Assessment of the Safety and Effectiveness of Venezuelan Equine Encephalomyelitis Vaccine, Inactivated, Lot C-84-6, TSI-GSD 205 as a Booster in At-Risk Personnel, IND 914

(5) **Start Date:**
Unknown

(6) **Est Compl Date:**
Inactive at present time.
IND protocol current.

(7) **Principal Investigator:**
Steven Boyea, CPT, MC

(8) **Facility:** FAMC
US Army Health Clinic
DPG

(9) **Dept/Svc:**

(10) **Associate Investigators:**

(11) **Key Words:**

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** Jan b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** 0
d. **Total Number of Subjects Enrolled to Date:** 15
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** Surveillance program to protect high risk workers.

(16) **Technical Approach:** Administered by U.S. Army Research Institute for Infectious Disease.

(17) **Progress:** Endpoint of this study has not been reached. No new enrollments for this reporting period.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 89/904 (3) Status: Completed

**(4) Title: Use of the Sixteen Personality Factor Questionnaire
to Predict Susceptibility to Occupational Stress
Among US Army Recruiters**

(5) Start Date: Aug 89

(6) Est Compl Date: Aug 90

**(7) Principal Investigator:
John Kaicher, CPT, MC**

**(8) Facility: FAMC
US Army Health Clinic
Ft. Sheridan, IL**

(9) Dept/Svc:

**(10) Associate Investigators:
Peter Orris, MD, MPH and
Robert Moretti, PhD,
Northwestern University
Medical School
Walter Teachout, CPT, MS, FAMC**

**(11) Key Words:
occupational stress
Army recruiters
personality factors**

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

***Refer to Unit Summary Sheet of this Report**

**(14) a. Date, Latest IRC Review: AUGUST b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for
studies conducted under an FDA-awarded IND. May be continued on a
separate sheet, and designated as "(14)e"**

**(15) Study Objective: To determine a mechanism to identify those
soldiers who are predisposed to disabling occupational stress problems,
considerable psychopathological morbidity and its attendant costs.**

**(16) Technical Approach: To determine the validity of the 16PF to
predict Army Recruiters predisposed to occupational stress related
psychological and behavioral problems.**

(17) Progress: Project was completed.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 90/900 (3) **Status:** Terminated

(4) **Title:** Iron Deficiency Anemia in 11-14 Month Old Infants at 6,000 Feet (1830m) Elevation. A Study to Evaluate the Response to a Therapeutic Trial of Iron

(5) **Start Date:** 1991

(6) **Est Compl Date:** 1992

(7) **Principal Investigator:**
Steve Lang, MAJ, MC

(8) **Facility:** FAMC
Ft. Carson, CO
Family Practice

(9) **Dept/Svc:** Ft. Carson

(10) **Associate Investigators:**
Joe Cravlo, CPT, MC
Ft. Carson, CO
Ray Yips, MD, MPH, CDC
Atlanta, GA

(11) **Key Words:**
anemia
infants
high altitude

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report

(14) a. **Date, Latest IRC Review:** AUG b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** 130
e. **Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"**

(15) **Study Objective:** To determine whether one year old infants at higher altitudes are more likely than children at sea level to be iron deficient.

(16) **Technical Approach:** Hemoglobin response in healthy 11-14 month old infants living at altitude to 3-month oral iron treatment will be assessed using a HemoCue hemoglobin measuring instrument.

(17) **Progress:** Approximately 130 subjects were enrolled. Patients were lost to follow-up and/or would not return. There were 35-40 returnees, but not enough for statistically significance.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/902 (3) Status: Ongoing

(4) Title: Administration of Equine Heptavalent Antitoxin for Therapy of Suspected Botulism Intoxication

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: Steven Boyea, CPT, MC (8) Facility: USAMRIID

(9) Dept/Svc: (10) Associate Investigators: Mark Clyde, CPT, MC, Dugway PG
Shannon Harrison, LTC, MC, C, DCI, FAMC
(11) Key Words: antitoxin
botulism

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review: Jul b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: The principle objective is to provide the depeciated botulinum antitoxin to individuals who may be exposed to botulinal toxins by foodborne, parenteral, or aerosol routes. A secondary objective is the collection of information regarding reactogenicity and efficacy of the product in humans.

(16) Technical Approach: Per Medical Research Institute of Infectious Diseases protocol IND 3703.

(17) Progress: None. Protocol recently approved by OTSG.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 91/950A (3) Status: Ongoing

(4) Title: Postgraduate Course on Obstetric, Neonatal, and Gynecologic Care: Resuscitation of the Newborn Utilizing the Ferret Model

(5) Start Date: 1991 (6) Est Compl Date: Indefinite

(7) Principal Investigator: (8) Facility: FAMC
Thomas Harris, MD, FAAP, Director, Perinatal Center, St. Mary's
Hospital, Grand Junction, CO

(9) Dept/Svc: (10) Associate Investigators:

(11) Key Words:
training

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studies conducted under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e"

(15) Study Objective: To provide a live, realistic animal model for teaching the life-saving skill of neonatal endotracheal intubation to Indian Health Service (IHS) personnel newly assigned to remote Service Units where successful resuscitation of asphyxiated infants may depend on their ability to intubate.

(16) Technical Approach: Per protocol approved by the LACUC on 15 Aug 91.

(17) Progress: 61 RNs and 43 MDs each attended one of the 6 50-minute workshops held on 9/27/91 in which the ferret model was utilized to teach endotracheal intubation techniques useful in new born resuscitation of humans.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/901 (3) Status: Ongoing

(4) Title: Army Pregnancy Study

(5) Start Date: 1992

(6) Est Compl Date: 1995

(7) Principal Investigator:
Joseph Creedon, Jr., CPT, MC

(8) Facility: FAMC
Ft. Carson, CO
Evans Army Community Hospital

(9) Dept of Occupational Health

(10) Associate Investigators

(11) Key Words:
reproductive outcome
occupational factors

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: MAY b. Review Results: _____

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: _____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: The purpose of this current investigation is to attempt to quantify risk to the offspring of female soldiers in the U.S. Army by CMF and MOS for the following outcomes: spontaneous abortions, ectopic pregnancies, intrauterine fetal demise, preterm birth, low birth weight infant, preterm and low birth weight infant, and congenital abnormalities.

(16) Technical Approach: Initially to be conducted as a pilot study at Evans ACH. Multi-center demographic questionnaire will be performed on study group comprised of female soldiers and the comparison group will consist of wives of soldiers.

(17) Progress: Previously titled "Soldier Adverse Reproductive Outcome Study", title changed per IRC recommendation. No progress to date due to special assignment of principal investigator. Study should start in calendar year 1993.

Publications and Presentations: None.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) **Date:** 30 Sep 92 (2) **Protocol #:** 92/902 (3) **Status:** Pending

(4) **Title:** Non-Thermal Pulsed Electromagnetic Energy (Diapulse)
in the Functional Rehabilitation of Ankle Sprains

(5) **Start Date:** 1992

(6) **Est Compl Date:** 1992

(7) **Principal Investigator:**
Gerard Pennington, MAJ, MC

(8) **Facility:** FAMC
Evans Army Community Hospital
Ft. Carson, CO

(9) **Dept of Orthopedics**

(10) **Associate Investigators**
Jeffrey Ginther, MAJ, MC
John Obusek, MAJ, MCS
David Danley, LTC, MSC

(11) **Key Words:**
ankle sprains
electromagnetic pulse

(12) **Accumulative MEDCASE:***

(13) **Est Accum OMA Cost:***

*Refer to Unit Summary Sheet of this Report.

(14) a. **Date, Latest IRC Review:** MAY b. **Review Results:** _____
c. **Number of Subjects Enrolled During Reporting Period:** _____
d. **Total Number of Subjects Enrolled to Date:** _____
e. **Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) **Study Objective:** Assess and measure objectively the effect of Diapulse on the decrease of rehabilitation and functional recovery time due to reduction of edema following ankle sprains.

(16) **Technical Approach:** Randomized, placebo-controlled trial of 50 subjects.

(17) **Progress:** IRC stipulations for approval have not been met. MAJ Pennington has PCS'd and a new PI has not been appointed. No progress.

Publications and Presentations:

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/903 (3) Status: Terminated

(4) Title: The Personal Family, Work and Social Impact of Reserve Medical Unit Soldiers and Their Families Deployed for Desert Shield/Storm in a Support Zone and in a War Zone.

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Fran Nelson, LTC, USAR, ANC

(8) Facility:
44th General Hospital
Det.1, 993 3rd St.
Menasha, WI 54952

(9) Dept of Nursing

(10) Associate Investigators

(11) Key Words:

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective:

(16) Technical Approach:

(17) Progress: The IRC reviewed and approved with study with multiple stipulations, which to date have not been met. This protocol was submitted for DA Nursing Research Funds. Funds were denied; therefore, the study will not be performed.

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: 92/904 (3) Status: Ongoing

(4) Title: The Effect of Placing Infants in Bed Awake at Night on Infant's Sleep Pattern.

(5) Start Date: 1992

(6) Est Compl Date: 1993

(7) Principal Investigator:
Helen Cook, MAJ, AN

(8) Facility:
Evans Army Community Hospital
Ft. Carson, CO 80913

(9) Dept of Nursing

(10) Associate Investigators
Ruth Crutchfield, PNP
Shirley Stewart, PNP
Carol Wetzig, PNP

(11) Key Words:
infants
sleep pattern

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: July b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 51
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Teaching the infant at an eraly age to sleep through the night will reduce family stress and possibly reduce child abuse.

(16) Technical Approach: Pilot project using 25 subjects for control and intervention groups.

(17) Progress: Enrollment is good, but due to excessive drop out rate, numbers are not accruing. Twenty of the 51 enrolled withdrew.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-1-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 22 Oct 91

(6) Est Compl Date:

(7) Principal Investigator:
Michael McCormick, MAJ, MC

(8) Facility: FAMC

(9) Dept of Med/Infect Dis

(10) Associate Investigators

(11) Key Words:
IND
HA-1A

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Dec b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-2-92 (3) Status: Completed

(4) Title: An Open Label Study of the Use of Azithromycin in Patients with Symptomatic Disseminated Mycobacterium Avium-Intracellulare Complex (MAC) Infection Failing Current Therapy, Protocol #066-162.

(5) Start Date: 30 Oct 91 (6) Est Compl Date:

(7) Principal Investigator: W.R. Byrne, LTC, MC (8) Facility: FAMC

(9) Dept of Med/Infect Dis (10) Associate Investigators

(11) Key Words:
IND
Azithromycin

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: March b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: See protocol.

(17) Progress: Patient expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-3-92 (3) Status: Ongoing

(4) Title: Itraconazole Compassionate Clearance Protocol (JRD 51,211/CC)

(5) Start Date: 5 Dec 91

(6) Est Compl Date: Dec 92

(7) Principal Investigator:
George Giacoppe, MAJ, MC

(8) Facility: FAMC

(9) Dept of Med/Pul

(10) Associate Investigators
Daniel Ouellette, MAJ, MC

(11) Key Words:

IND

itraconazole

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Treatment of semi-invasive pulmonary aspergillosis.

(16) Technical Approach: 200 milligrams per day for one year

(17) Progress: Patient has been taking itraconazole since 5 Dec 91 without apparent ill effect. He reports no adverse effect. His hemoptysis has cleared with the exception of one minor episode in mid-January. He has no fever, chills, or night sweats. His laboratory studies are normal and his chest x-ray has shown a resolution of an air fluid level in a cavity in the left upper lung field (CXR dated 12/19/91) on therapy; a subsequent film (1/16/92) showed a decrease in the size of the cavity with increasing pleural reaction. No plans at present to change his dose or discontinue the medication.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-4-92 (3) Status: Completed

(4) Title: 2-Chloro-2-deoxyadenosine (2CdA) for treatment of Hairy Cell Leukemia (NCI Protocol #E91-7197)

(5) Start Date: 14 Jan 92 (6) Est Compl Date: 21 Jan 92

(7) Principal Investigator: David Faragher, MAJ, MC (8) Facility: FAMC

(9) Dept of Med/Hem-Onc (10) Associate Investigators

(11) Key Words:
IND
2-CdA

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Per study title.

(16) Technical Approach: 2-CdA 0.1 mg/kg/d for 7 days administered by continuous intravenous infusion for one cycle only.

(17) Progress: Patient tolerated the treatment well and was discharged from the hospital on 26 Jan 92 in good condition. Patient is followed on a regular and frequent basis with continual improvement. It is apparent through reevaluation pathis has had a partial response to therapy. He will receive on going reevaluation for HCL.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-5-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 3 Mar 92

(6) Est Compl Date:

(7) Principal Investigator:
Shannon Harrison, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/Infect Dis

(10) Associate Investigators

(11) Key Words:

IND

HA-1A

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Mar b. Review Results:

c. Number of Subjects Enrolled During Reporting Period:

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #:EU-6-92 (3) Status: Completed

(4) Title: I-131 MIBG (metaiodobenzylguanidine)

(5) Start Date: 27 Apr 92 (6) Est Compl Date:

(7) Principal Investigator: Albert Lambert, CPT, MC (8) Facility: FAMC

(9) Dept of Rad/Nuc Med (10) Associate Investigators

(11) Key Words:
IND

(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To enhance radiographic imaging for diagnostic purposes.

(16) Technical Approach: 204uCi injected intravenously

(17) Progress: Used to enhance imaging for diagnostic purposes.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-7-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 23 Apr 92

(6) Est Compl Date:

(7) Principal Investigator:
Phillip Mallory, LTC, MC

(8) Facility: FAMC

(9) Dept of Surgery

(10) Associate Investigators
Samuel Cucinell, COL, MC

(11) Key Words:
IND
HA-1A

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient survived. Drug treatment completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-8-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 23 Apr 92

(6) Est Compl Date:

(7) Principal Investigator:
Phillip Mallory, LTC, MC

(8) Facility: FAMC

(9) Dept of Surgery

(10) Associate Investigators

(11) Key Words:
IND
HA-1A

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Apr b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-9-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 22 May 92

(6) Est Compl Date:

(7) Principal Investigator:
Sharon Hammond, MAJ, MC

(8) Facility: FAMC

(9) Dept of Surgery

(10) Associate Investigators

(11) Key Words:
IND
HA-1A

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IR/ Review: May b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient expired.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-10-92 (3) Status: Completed

(4) Title: Open Label Trial of Centoxin (HA-1A) Treatment of Presumed Gram-Negative Sepsis (C0041T07)

(5) Start Date: 5 June 92 (6) Est Compl Date:

(7) Principal Investigator: Jeffrey Clark, COL, MC (8) Facility: FAMC

**(9) Dept of Surgery (10) Associate Investigators
H.W.Hollis, MD**

**(11) Key Words:
IND
HA-1A**

**(12) Accumulative MEDCASE:* (13) Est Accum OMA Cost:*
*Refer to Unit Summary Sheet of this Report.**

**(14) a. Date, Latest IRC Review: May b. Review Results:
c. Number of Subjects Enrolled During Reporting Period:
d. Total Number of Subjects Enrolled to Date: 1
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".**

(15) Study Objective: As per title.

(16) Technical Approach: 100 milligrams

(17) Progress: Patient survived. Drug treatment completed.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-11-92 (3) Status: Ongoing

(4) Title: Single Patient Protocol for the Clinical Evaluation of Itraconazole (R51,211/CC) in the Compassionate Clearance Treatment of Systemic Mycoses

(5) Start Date: 22 Jun 92

(6) Est Compl Date:

(7) Principal Investigator:
Robert Gates, LTC, MC

(8) Facility: FAMC

(9) Dept of Med/Infect Dis

(10) Associate Investigators

(11) Key Words:

IND

Itraconazole

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Jun b. Review Results: Approved

c. Number of Subjects Enrolled During Reporting Period: _____

d. Total Number of Subjects Enrolled to Date: 1

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: As per study title.

(16) Technical Approach: 100 mg q.d.

(17) Progress: The patient continues on treatment.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-12-92 (3) Status: Completed

(4) Title: Strontium-89 Therapy

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Morakinyo Toney, LTC, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators

(11) Key Words:

IND
strontium-89

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To decrease pain associated with the diagnosis and improved quality of life.

(16) Technical Approach: 40 microcuries/kg as a single dose

(17) Progress: Drug administered 16 Jul 92. Patient was pain-free from his bone metastasis after treatment and until his death. This treatment was considered a success.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-13-92 (3) Status: Completed

(4) Title: Strontium-89 Therapy

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Albert Lambert, MAJ, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators

(11) Key Words:

IND

strontium-89

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____

b. Review Results:_____

c. Number of Subjects Enrolled During Reporting Period:_____

d. Total Number of Subjects Enrolled to Date:_____

e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To decrease pain associated with the diagnosis and improved quality of life.

(16) Technical Approach: 40 microcuries/kg as a single dose

(17) Progress: Drug use approved on 7 Aug 92 and administered 12 Aug 92. Although patient did not achieve complete relief of his bone pain after the Strontium-89 injections, his narcotic requirement was greatly reduced and his ability to ambulate as well as his quality of life remarkably improved prior to his death. As such this treatment was considered a success.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-14-92 (3) Status: Completed

(4) Title: Murine Anti-CEA Conjugated to Indium-111

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Brad Bute, MAJ, MC

(8) Facility: FAMC

(9) Dept of Surgery

(10) Associate Investigators

(11) Key Words:
IND

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Use for diagnosis and localization of tumor.

(16) Technical Approach: Single injection of 5 millicuries (with a total body dose of 2.33 rads) with camera scans at 3, 5, and 7 days, with an effective dose equivalent of fewer microcuries.

(17) Progress: Approved on 13 Aug 92 for emergency use in two patients. Protocol will be reviewed by the IRC in Oct 92 to facilitate use in multiple patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-15-92 (3) Status: Completed

(4) Title: Murine Anti-CEA Conjugated to Indium-111

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Brad Bute, MAJ, MC

(8) Facility: FAMC

(9) Dept of Surgery

(10) Associate Investigators

(11) Key Words:
IND

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review:_____ b. Review Results:_____
c. Number of Subjects Enrolled During Reporting Period:_____
d. Total Number of Subjects Enrolled to Date:_____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: Use for diagnosis and localization of tumor.

(16) Technical Approach: Single injection of 5 millicuries (with a total body dose of 2.33 rads) with camera scans at 3, 5, and 7 days, with an effective dose equivalent of fewer microcuries.

(17) Progress: Approved on 13 Aug 92 for emergency use in two patients. Protocol will be reviewed by the IRC in Oct 92 to facilitate use in multiple patients.

Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-16-92 (3) Status: Completed

(4) Title: Strontium-89 Therapy

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
Albert Lambert, MAJ, MC

(8) Facility: FAMC

(9) Dept of Radiology

(10) Associate Investigators

(11) Key Words:

IND

strontium-89

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: _____ b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To decrease pain associated with the diagnosis and improved quality of life.

(16) Technical Approach: 40 microcuries/kg as a single dose

(17) Progress: Drug use approved on 13 Aug 92.
Publications and Presentations: None

FAMC A.P.R. (RCS MED 300) Detail Summary Sheet (HSCR 40-23 as amended)

(1) Date: 30 Sep 92 (2) Protocol #: EU-17-92 (3) Status: Terminated

(4) Title: Itraconazole

(5) Start Date:

(6) Est Compl Date:

(7) Principal Investigator:
W. Russell Byrne, LTC, MC

(8) Facility: FAMC

(9) Dept of Medicine

(10) Associate Investigators

(11) Key Words:

IND
itraconazole

(12) Accumulative MEDCASE:*

(13) Est Accum OMA Cost:*

*Refer to Unit Summary Sheet of this Report.

(14) a. Date, Latest IRC Review: Oct b. Review Results: _____
c. Number of Subjects Enrolled During Reporting Period: _____
d. Total Number of Subjects Enrolled to Date: _____
e. Note any adverse drug reactions reported to the FDA or sponsor for studying under an FDA-awarded IND. May be continued on a separate sheet, and designated as "(14)e".

(15) Study Objective: To treat pulmonary coccidiomycosis.

(16) Technical Approach: 200 mg/day for up to 12 months.

(17) Progress: Decided not to obtain or use drug.

Publications and Presentations: None

INVESTIGATORS INDEX

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